

**U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Industry Activities Section
1994**

Do Your Own Establishment Inspection

A Guide to Self Inspection for the Smaller Food Processor and Warehouse

Why This Booklet?

The Food and Drug Administration (FDA) considers establishment inspection one of its prime enforcement tools. During 1980, FDA made over 25,000 inspections of food plants and warehouses. Clearly, this is an important way of determining whether or not food firms are in compliance with the FDA's law and regulations. Many of the regulatory actions FDA takes against food firms are based on FDA's findings during inspections.

By inspecting your own establishment, you can see if your operation could face regulatory problems. This booklet will aid you in performing a check of your own operations so that the FDA inspection will not necessarily surprise you with its findings. While not a substitute for the FDA establishment inspection, conducting your own "self inspection" can help you to detect and solve compliance problems you might have before they get out of hand.

This booklet tells you --

- why you should be fully aware of your firm's problem areas
- what problems you will face as you conduct your inspection
- how to make your own establishment inspection

Why You Should Be Fully Aware of Your Plant's Problem Areas

- **It's Good Business**

No one wants to deal with poor merchandise. If your business gets a reputation for being shoddy, dirty or otherwise negligent, your prospective customers will seek greener--at least, cleaner--pastures. It makes good business sense to keep your operation healthy and reputable. Safe, quality foods help you do this.

- **It's Your Responsibility**

The food laws and regulations that FDA enforces apply to firms that receive or ship food in interstate commerce. The requirements place the prime legal responsibility for safe, quality foods, adequately labeled, upon you, the food processor. If you just store foods, you too are legally bound to prevent contamination of the food while it is in your possession. This is the law.

• It Can Keep You Out of Trouble

The FDA *does* enforce the law. If your facilities are found to be out of compliance with the Federal requirements for proper food processing and warehouse storage practices, you can face any number of Federal actions. These include:

Notice of Adverse Findings Letter: Issuance of this official correspondence, while not considered a regulatory action, indicates FDA's awareness of a violation that must be corrected.

Regulatory Letter: A formal notification that the FDA is prepared to take a legal action if the violations cited in the letter are not corrected immediately.

Seizure: This is a civil court action against a specific lot of goods to remove them from the channels of commerce. Seizure actions are concerned primarily with the confiscation of food products which are in violation of the law and with the condemnation and destruction or reconditioning of these products.

Prosecution: Criminal action taken against a firm responsible for causing the charged violations of law. A first offense can draw one year in prison, \$1,000 fine, or both, on each count or proven violation. A second offense can mean a sentence of three years in prison and \$10,000 for each count. A first offense with intent to defraud or mislead is subject to imprisonment for not more than three years, or a fine of \$10,000, or both for each offense.

Injunction: A decree that restrains the defendants from engaging in violative food processing or warehouse practices and remains in force until termination. This would occur if the firm has a history of insanitary problems or when there is a health hazard involved with the operation.

• It Isn't That Hard

In terms of cost and manpower, self inspection is the most reasonable means of helping to ensure a satisfactory food processing and storage operation, *and* a "clean bill of health" from the FDA. By taking the time and effort to inspect your operations on a regular basis, you have the opportunity to correct potential problems and safeguard your investment.

The Problem Areas: What You Are Up Against

There are seven problem areas that, if left unwatched and unchecked, can become severe hindrances in your efforts to maintain a sanitary food operation free of compliance problems.

First is the **rodent** (usually, rats and mice). Rodents carry many diseases and parasites which, because of their biological similarity to people, can be transmitted to man. These diseases and parasites include leptospirosis (Weil's Disease), salmonellosis, tapeworms, trichinosis and others.

Rodents will deposit excreta, urine and other filth on food products and around your facilities. They will also gnaw on materials in order to build nests. Rodents contaminate much more than they eat.

Against rodents, you cannot take the security of your plant or firm for granted. Some rodents can walk along telephone wires or leap horizontally 18 feet. They can squeeze through gaps the width of a pencil or drop 50 feet without being killed. Their instinct for survival is high, and they can deviate from "normal" behavior patterns to trick man. They are extremely prolific creatures, and once they've infiltrated your operations, your problems will multiply!

Birds also carry diseases and parasites potentially hazardous to people. They are capable of flying

through any open window, door or other gaps in your building, and, like rodents, will leave insanitary droppings that can contaminate your plant and your food products.

Insects seek heat, moisture and darkness, and once in, can be even more elusive than rodents or birds. However, they aren't invisible--they leave trails in the dust, and can also be spotted around likely insect hideouts: holes, damp places, behind boxes and in seams in bags and folds of paper. Like rodents, some insects--notably cockroaches--have a highly developed survival instinct and they are adaptable--they can develop an immunity to poisons you use within a few insect generations. They are even more prolific than rodents. With their hairy legs, they spread dirt, debris and bacteria around your firm. They carry either within or outside of their bodies the causes for many serious diseases and ailments such as boils, food poisoning and typhoid fever.

In dealing with any of the above pest problems, you may want to try to cope with them on your own, but it is highly recommended that you seek the help of a good pest control operator, or "exterminator." The results will probably be better, and in the long run, this may be a more cost effective method.

If you were to take all the rodents and insects in the world, they would be outnumbered by the **bacteria** to be found in one vat of spoiled egg batter. Bacteria are a worse problem than any of the previously mentioned creatures because they can't be seen, yet they can sicken or kill just the same.

Bacteria cannot be eliminated, but they *can* be defeated. Like any creatures, bacteria need a combination of food, water and the proper temperature to survive. By regulating the availability of each, you can take a big step toward keeping their population down.

Molds will grow on almost anything, especially where there is moisture. The presence of mold in a product is an indication that the product contains excessive decomposed material and may also indicate insanitary practices on the part of the processor. Molds can make you ill, and scraping off mold or getting rid of the one "bad apple" doesn't always solve the problem.

While the other problem areas are active, aggressive opponents, **chemical contaminants** can only become a problem through misuse or neglect--yet the end result of their presence can be equally disastrous. Still, this is one of the easier problems to control.

This brings us to the seventh problem area--ignorance and carelessness. As a problem, this can be just as dangerous as any of the preceding, but it can be combated by applying the guidelines given in this booklet, and by just using common sense. Now, let's get on with the tactics for waging an offensive against the problems.

Police the Area--Know What's in Your Plant

Self-inspection is a most cost effective way for you to maintain a firm that is in compliance with federal requirements for food processing and storage. By assuming the role of an investigator, you can uncover potential problems and solve them before they become *big* problems.

Let's "walk" through an operation--your operation--using the following checklist to investigate major areas of concern. This checklist can serve as a basic guide to help you maintain or improve compliance with federal requirements and to ensure that only safe, quality products reach the consumers.

Here are some pointers for using the checklist:

1. Check the box beside each item to indicate a "situation under control," or one that needs

further attention.

2. Use the space provided at the end of each topic section to note what you intend to do to correct an identified problem, and to note any compliance problems you face that are not addressed by the checklist. This checklist is a *guide* to be developed according to the needs of your operation.
3. Feel free to photocopy this checklist and to use it regularly during your inspections.

Employees

We'll begin the check with your employees. They are your most important resource.

OK		Needs Attention
<input type="checkbox"/>	<ul style="list-style-type: none"> • Are the employees well-trained in what they do? You can avoid many problems by making sure that your employees clearly understand their functions. 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • In handling food products, do your employees wear the proper hair covering and clean uniforms? 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Are your employees wearing jewelry, bandages, or have any illnesses, infections or injuries (i.e., boils, cuts) which can contaminate foods? 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Do your employees wash after each visit to the toilet? <ul style="list-style-type: none"> • Do you have washing facilities available for your employees near their work stations, and do they use them when their hands become soiled or contaminated? • You must display "reminder" posters in your rest rooms for employees to wash their hands. 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Do your employees maintain clean personal habits? They should keep their hands away from body surfaces, which are loaded with bacteria. 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Is the traffic within your plant controlled to prevent contamination of the processing areas? 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Have your employees been told the reasons why they should undertake the above precautions? 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Other Employee practices that need attention: <hr style="border: 0; border-top: 1px solid black; margin-top: 10px;"/> <hr style="border: 0; border-top: 1px solid black; margin-top: 10px;"/> <hr style="border: 0; border-top: 1px solid black; margin-top: 10px;"/> <hr style="border: 0; border-top: 1px solid black; margin-top: 10px;"/>	<input type="radio"/>

Plant/Grounds

OK		Needs Attention
<input type="checkbox"/>	<ul style="list-style-type: none"> • Is the area around your firm clear of weeds, grass and brush? This sort of foliage can be an effective cover for pests to infiltrate your firm. 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Is there any standing water on your ground which also attracts pests? 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Other outside Plant conditions that I want to look into: <hr style="border: 0; border-top: 1px solid black; margin-top: 5px;"/> <hr style="border: 0; border-top: 1px solid black; margin-top: 5px;"/> <hr style="border: 0; border-top: 1px solid black; margin-top: 5px;"/> <hr style="border: 0; border-top: 1px solid black; margin-top: 5px;"/>	<input type="radio"/>

Building/Facility

OK		Needs Attention
<input type="checkbox"/>	<ul style="list-style-type: none"> • Do windows and doors seal tightly to ward off pests and contaminants? 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Do windows have fine mesh screens to keep out insects? 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Will a pencil pass under the door? That's all the space required for a rodent to enter. 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Have all holes and cracks been filled so as not to provide hiding places or entry points for pests? 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Not only should your firm be free of vermin and pests--there shouldn't even be evidence of the presence of domestic animals such as cats and dogs. 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Are rest rooms cleaned regularly? 	<input type="radio"/>
<input type="checkbox"/>	<ul style="list-style-type: none"> • Are the hand-washing facilities furnished with paper or air hand dryers and soap? 	<input type="radio"/>
	<ul style="list-style-type: none"> • The hand-washing facilities should be furnished with running water at a suitable temperature for washing hands. 	

- They should provide effective hand-washing and sanitizing preparations.

• Does the roof leak? This can add to the problems of humidity, standing water and product contamination.

• Are the overhead lights covered with shields to prevent contamination of products by broken glass in case the lamps burst?

• Other **Building/Facility** problems that need to be addressed:

Equipment

OK

**Needs
Attention**

• Is all equipment which comes in contact with food cleaned and sanitized as often as necessary to prevent contamination of the product? You should follow appropriate cleaning schedules for each piece of equipment.

• Is the equipment designed, or otherwise suitable, for use in a food plant? For example, equipment for handling or processing foods cannot contain polychlorinated biphenyls (PCB's), which are very toxic (this does not apply to electrical transformers and condensers containing PCB's in sealed containers).

• Is there a build-up of food or other static material on the equipment? This can serve as a breeding place for insects and bacteria.

• Is there any build-up or seepage of cleaning solvents or lubricants on your equipment which can contaminate foods? All repairs on equipment should be of a permanent nature (e.g., no bobby pins in place of cotter pins), as temporary repair parts can break or rupture and get in the food product.

• Is the equipment hard to disassemble for clean-up and inspection? The more difficult it is, the less inclined you or an employee will be to clean it.

• Is there a lot of "dead space" in or around the machinery where food and other debris can collect as a nest for insects and bacteria?

• Can the surface of the equipment be sanitized? Wood is one

material that cannot.

- Other **Equipment** cleaning and maintenance issues that should be covered:
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Housekeeping

OK

**Needs
Attention**

- Are trash, debris, and clutter picked up so as not to provide hiding places for pests?
 - Do employees eat and smoke only in designated areas?
 - Is the food spilled or uneaten by employees cleaned up quickly so as not to attract pests or breed bacteria?
 - Has old rodent excreta been cleaned up so you can spot any new activity?
 - Additional **Housekeeping** duties that must be attended to:
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Garbage

OK

**Needs
Attention**

- Is garbage quickly removed and dumped in appropriate bins? It should not sit around your facilities to attract pests.
- Is the garbage kept covered? An open garbage pile is an excellent breeding ground for insects and rodents.

- Other **Garbage**-handling problems that should be explored:
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Plumbing

OK

**Needs
Attention**

- Is the water used in your firm from an approved source (either municipal supply or tested private source)?
 - Have you made sure there are no hoses left dangling in sinks or on the ground? Loss of pressure can cause a back flow that will contaminate your water supply.
 - Do your facilities have back flow and vacuum breaker valves to prevent contaminate your water supply?
 - Avoid standing water around your firm.
 - Other **Plumbing** needs that require attention:
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Humidity

OK

**Needs
Attention**

- Does your building have dripping condensation or leaky plumbing which can contaminate foods?
- Are you keeping the humidity in your operation low? Molds, insects and bacteria thrive in damp climate.
- Other problems to attend to regarding **Humidity**:

Temperature

OK

**Needs
Attention**

- Are storage areas intended for room temperature subject to extremes of temperature, either hot or cold? This can damage foods.
 - For refrigeration storage, coolers should be kept at or below 40 degrees F.
 - For freezer storage, the temperature should be kept at or below 0 degrees F.

- Are you keeping a record of temperatures for all storage areas on a regular basis?

- Are you keeping your facilities at the proper temperature range? Insects love high temperatures, and their activity will pick up as the temperature goes up.

- Additional **Temperature**-related difficulties to explore:

Incoming Raw Materials

OK

**Needs
Attention**

- Have you checked to see that the compartment door seals on the truck are intact?

- Is there a clean smell when the compartment doors are opened, or are there signs of contamination such as petroleum distillate, putrefaction, or other off-odors?

- Is any refrigerated compartment set at the proper temperature?
- Are boxes properly stacked and intact?
- Is there evidence of activity by insects, rodents or birds?
- Is there evidence of the misuse of pesticides such as DDT tracking powder, 1080, or insect sprays?
- Additional problems that should be dealt with on **Incoming Raw Materials:**

The FDA publication *Inspecting Incoming Food Materials* will provide further information on conducting an inspection of incoming food materials.

Storage of Raw Materials and Products

OK

Needs Attention

- Is the storage area over-crowded? Such a condition prevents adequate inspection and clean-up and also increases the likelihood of damage to products during handling.
- Are products stored on pallets and at least 18 inches away from the walls? It is important to leave space for inspection aisles so that rodent and insect activity can be seen more readily. You might consider painting a white line on the floor along the walls to indicate inspection aisles.
- Other **Storage** problems that should be corrected:

Rotation

OK

**Needs
Attention**

- Are products stored on a first-in, first-out basis to reduce the possibility of contamination through spoilage?
 - Are old products kept in front of the new to help in the rotation process?
- Are all incoming products dated to ensure a proper rotation of stocks?
- Are items overstocked? This increases the chances of spoilage and contamination.
- When checking containers for contamination, are dusty, faded or discolored containers checked first? They are obviously the most suspect items.
- Additional issues to address on the **Rotation** process:

Quarantine

OK

**Needs
Attention**

- Are all products spoiled by damage, insects, rodents or other causes stored in a designated "Quarantine Area" to prevent their contact with safe products?
- Are such quarantined items disposed of quickly to prevent the development of pest breeding places?
- Are incoming materials inspected for damage or contamination so that they can be rejected?
- Other problems to address in the **Quarantine** procedure:

Pest Control

OK

**Needs
Attention**

If you hire an outside pest control operator, you should:

- Check regularly on what the pest control operator is doing. Don't accept what he's doing on faith.
- Check to see what poisons he is using. Make sure the poisons do not contaminate foods.
- Learn where and how many bait stations there are.
 - They should be placed so as not to present any chance of food contamination.
 - They should be checked regularly.
- Check to see if fumigators are being used. Do they represent a hazard to employees or food safety?

If doing your own exterminating, you should:

- Know there is no such thing as an all-purpose pesticide, especially where foods are concerned. Get qualified advice before using any poisons.
- Make a map showing locations of all traps, bait stations, etc., and check them regularly.
- Put money into building maintenance if that will help solve your pest problems. For instance, don't rely solely on rodenticides to control your pest problem and leave gaps in the doors for the rodents to enter. Make sure those gaps are sealed. Extermination is a poor second choice, and will cost you as much, or more, in the long run.
- Other **Pest Control** situations to explore:

Storage and Handling of Hazardous Materials

OK

**Needs
Attention**

- Are materials such as pesticides, herbicides, cleaning solvents, lubricants and boiler compounds accessible for use only by authorized employees? This will help prevent accidents such as food contamination and employee injuries due to ignorance and misuse.
 - Additional situations to consider regarding **Hazardous Material Storage**:
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Labeling

OK

**Needs
Attention**

- Are all hazardous materials kept in bottles, or drums, or boxes that reflect their dangerous nature?
 - Even non-hazardous materials should be labeled correctly. Several babies died in a hospital because salt was mistakenly used for sugar in their formulae.
 - Make sure that any labels you market comply with the Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act.
 - Other questions on **Labeling** that need to be considered:
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FDA does not have the authority to approve labels prior to marketing, but it does have jurisdiction once the label is in interstate commerce. FDA will take legal action if a product is not labeled in accordance with the law. FDA is willing to provide comments on your labeling prior to marketing, if you desire.

Food Additives

OK

**Needs
Attention**

• Make certain that the food additives you use are suitable and safe for the intended purposes.

• Other issues regarding **Food Additives** to be resolved:

Product Codes

OK

**Needs
Attention**

• Do you have an effective recall procedure set up?

• Other considerations on **Product Codes**:

By completing this brief inspection "patrol," you now have an idea of what the FDA investigator will generally look for when he visits your firm. This "short course" is far from complete, but it should provide a foundation to help you maintain a safe, quality food processing and storage operation.

Here are some last-minute hints to help you in your inspection and sanitation efforts:

1. As you inspect, use the checklist to make a record of the problems you encounter so you won't forget them. You can then make corrections based on the checklist.
2. Formulate inspection, clean-up and maintenance schedules and stick to them.
3. Define your employees' responsibilities; make sure each one understands his duties so that no essential details are ignored.
4. Be diligent in your sanitation efforts. The struggle to control pests, bacteria and the other problem areas is a fulltime effort.

You've just taken your first *big* step in the campaign for better food processing and storage. By

reading this booklet, you've gained an awareness of the problems you might face, tactics for dealing with them, and knowledge that FDA is ready to help you with advice and further information on how you can deal with specific problems you encounter.

By taking preventive measures now, you can avoid potentially costly, mandated adjustments that might arise when the FDA investigator pays you a visit--and you can ensure that only quality, safe food products find their way to the consumers...a move we all want.

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