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ABSTRACT

This workshop handbook contains information and reference materials on proper food warehouse sanitation. The materials have been used at Food and Drug Administration (FDA) food warehouse sanitation workshops, and are selected by the FDA for use by food warehouse operators and for training warehouse sanitation employees. The handbook is divided into three sections. The first section contains speeches given at food warehouse sanitation workshops. The speeches explain what the workshop is about, cover FDA requirements for sanitation control, and FDA regulatory procedures and inspections, as well as industry assistance. The second section of the publication contains reprints of two food warehouse sanitation articles on voluntary industry sanitation guidelines for food distribution centers and warehouses, and guidelines for sanitation inspection. The third section of the handbook is an annotated bibliography of publications and visual aids on food warehouse sanitation, with instructions on how to order the materials. (KC)

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WAREHOUSE SANITATION WORKSHOP HANDBOOK

This Workshop Handbook contains helpful information and reference materials on proper food warehouse sanitation. The material has been carefully selected for your use and as part of your warehouse sanitation employee training program.

The materials in this handbook have been used at FDA Food Warehouse Sanitation Workshops. The handbook will be updated as new materials become available.

U S DEPARTMENT OF HEALTH,
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PREPARED BY INDUSTRY PROGRAMS BRANCH, BUREAU OF FOODS



TABLE OF CONTENTS

FOOD WAREHOUSE SANITATION SPEECHES

"What This Workshop is All About".....	9
"FDA Requirements - Sanitation Control".....	13
"FDA Regulatory Procedures".....	17
"FDA Inspections - Approach and Identified Problems".....	25
"FDA Industry Assistance".....	33

REPRINTS OF FOOD WAREHOUSE SANITATION ARTICLES

"Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses".....	37
"Guidelines for Sanitation Inspection".....	55

PUBLICATIONS AND VISUAL AIDS (HOW TO ORDER)

"Inspecting Incoming Food Materials".....	67
"Ten Rules for Food Warehousemen" - A Poster.....	68
"Warehouse Sanitation...You Are The Solution" -FDA Slide Series...	69
"Requirements of the Laws and Regulations Enforced by the U.S. Food and Drug Administration".....	70
"FDA Catalog of Food Industry Information Materials".....	71
"Pesticides...Read the Label First".....	72
"Safe Storage and Disposal of Pesticides".....	73
"How to Obtain FDA Regulations".....	74
"Beetle or Weevil?" - A Fact Sheet.....	75

WAREHOUSE SANITATION

SPEECHES

WHAT THIS WORKSHOP IS ABOUT

This workshop is about "sanitation." By the end of the day I hope you will leave committed to improving and maintaining at a high standard the level of sanitation in your food storage warehouse.

The sanitation of food cannot be separated from the sanitation of the environment which food products are stored, handled, produced, or prepared, and from the sanitary practices and personal hygiene of the people who handle the food.

Almost 10 years ago, food warehouse operators could expect a FDA sanitation inspection about once every six years. This rate of inspection was the result of agency resources being committed to other, more pressing problems. An increasing number of consumer and trade plus other evidence uncovered by FDA inspectors indicated a steady deterioration of food warehouse sanitation. To gauge the extent of the problem, FDA inspected a random sample of 3,000 dry-storage food warehouses.

SANITATION PROBLEM EXISTS

The United States General Accounting Office (GAO) conducted its own audit of establishments handling, storing, processing, and shipping food. The GAO report confirmed FDA's findings and concluded that a serious sanitation problem existed in the food industry throughout the country.

Recognition of these conditions prompted the House Appropriations Subcommittee, which handles FDA's budget, to provide very significant personnel and money increases in 1972 which were specifically earmarked for food sanitation inspections. This increased emphasis has helped improve the situation.

For example, since 1976, just over 10 percent of the inspected food warehouses had some enforcement actions taken against them. While this is a considerable improvement, the consuming public wants and has every right to expect better conditions than we find today.

SEIZURES REPRESENT DOLLAR LOSS

What might be of more interest to you are the approximate figures for quantity, and dollar value of merchandise seized in food warehouses during the period 1976 through 1978. These seizures were based upon violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The figures represent products that were unfit for food and/or may have become contaminated so that the product would be injurious to health. Seizures of lots of food stored in warehouses increased from 58 in 1976, to 79 in 1977, and to 122 in 1978, representing around 3,000 tons of food, worth about \$21 million dollars. This upward trend is continuing in 1979.

Food lost as a result of seizure actions could have been prevented. It represents an economic loss both to you, the warehouse operator, and to the American consumer. Seizure actions are necessary when food is adulterated by rats, mice, insects, birds and other animals, mold, or decomposition. The majority of these problems are particularly evident in the colder months when field animals usually seek the warmer and well-stocked warehouse environment for food and shelter. This phenomenon occurs each and every year, and, those who do not have a battle plan to combat it, - those who are not prepared to deal with it - are the ones who must face up to correcting the problem via regulatory action--seizure, injunction, or possibly prosecution.

Why are we holding this workshop? We want you to prevent and eliminate sanitation problems before they get out of control. We want you to exercise greater care and vigi-

lence over the quality and wholesomeness of food supplies under your care.

THIS RESPONSIBILITY IS YOURS

While FDA and the state of Mississippi have responsibilities in protecting the public health, you have the primary responsibility for establishing and maintaining sanitary conditions. FDA's consumer protection role in assuring the safety and sanitation of food stored in warehouses is to monitor your operations and to communicate with you. FDA's philosophy is that it would rather anticipate and prevent through monitoring and communicating than react and prevent through legal actions. However, the FDA has not and will not hesitate to take legal actions to correct a given situation. This is confirmed by FDA initiating criminal prosecution procedures against 79 food warehouse operators during the years 1976 - 1978. At least four such criminal actions have been instituted in this region alone during the past year.

FDA monitors your activities by comparing and analyzing them in accordance with the Current Good Manufacturing Practice regulations for the storing and holding of food. This workshop is an example of how FDA tries to communicate with industry. We believe that consumer protection can be enhanced through both industry communication and regulatory activities if necessary.

The state of Mississippi plays a similar and vital role in assuring the safety and wholesomeness of food. But you have the prime role in all of this. You must assure the integrity of the products in your warehouse.

FDA REGULATORY ENFORCEMENT

FDA's regulatory activities are based on the FD&C Act. This Act gives FDA authority to enter and to inspect at reasonable times and within reasonable limits and in a reasonable manner, warehouses in which food is processed, packed, or held for introduction into Interstate Commerce or after such introduction. In addition, the Act also empowers FDA to issue regulations for the enforcement of the Act. Of special importance and concern to you are the Current Good Manufacturing Practice regulations. The regulations identify the requirements for preventing foods from consisting of filthy, putrid, or decomposed substances. FDA uses its inspectional authority to collect evidence of violations of these regulations to help you maintain a sanitary warehouse, and to assure the consuming public of a safe food supply.

In determining whether or not conditions surrounding the storage of foods are unsanitary, it is necessary to evaluate the possibility of contamination with both foreign matter that may be harmless but disgusting with elements which involve danger to health. In its sanitary provisions, the FD&C Act goes further than just to prohibit commerce in products that are carriers of disease causing agents. It prohibits the distribution and sale of foods which may contain repulsive, or offensive matter, classified as filth. Distribution and sale of foods is prohibited regardless of whether such objectionable substances can be detected by laboratory procedures are likely to be present because of the conditions under which the goods were prepared and handled.

However, there is nothing highly technical in the concept of sanitation applied to the enforcement of the Act. Ability to conform to standards of storage that will result in a clean product does require a careful study of sources and routes of contamination. It is expected, of course, that establishments in which foods are stored will properly be constructed, lighted and ventilated; and that employees will be properly clothed and supervised.

Insanitary conditions are those which permit contamination by rodents, infestation by insects, defilement by birds, and pollution from human and other animal wastes. As warehouse operators you are primarily responsible for assuring the safety and sanitary quality of the food you receive, handle, store, and ship. It is up to you to resolve any problems in your operations which may be caused or affected by insanitary conditions. To do this you must:

- o Know your responsibilities under federal and state law;
- o Implement the current Good Manufacturing Practice Regulations;
- o Determine the sources, routes and types of contamination; and,
- o Institute an effective sanitation program.

We hope the rest of this workshop will give you some help in meeting these obligations.

FDA Presented by: M.D. Kinslow, Regional Food and Drug Director, Atlanta District, at Warehouse Sanitation Workshop, Jackson, MS, October 5, 1979.

FDA REQUIREMENTS SANITATION CONTROL

The Food and Drug Administration is responsible for enforcing the Federal Food, Drug, and Cosmetic Act. This law requires FDA to make certain that the food supply is safe to eat. It is this law that gives us the authority to come into your warehouse and make inspections.

FDA inspections are conducted to make sure there are no violations of the Federal Food, Drug, and Cosmetic Act. We have found that a large number of violations are committed through ignorance of this law. This presents a problem to you because you are still bound by the law whether or not you know the requirements. So, today we will attempt to explain parts of the law with particular importance to you as warehouse managers.

What I will do is go through provisions of the law of concern to your operations.

First, it will be useful to begin with the definition of a food as defined in Section 201(f) of the Federal Food, Drug, and Cosmetic Act. Food is defined in the Act as (1) articles used for food or drink for man or other animals, (2) chew-

ing gum, and (3) ingredients of any such article. For example, this definition would include such things as pet food, beverages, the chemicals used to preserve meats, spices, coffee, and so forth. As you see, the law covers a large number of products. You will also note that the Act makes no distinction between human and animal foods in the definition of food.

The law permits FDA investigators to inspect your warehouse at reasonable times to determine if there are violations of the Federal Food, Drug, and Cosmetic Act. These inspections would cover:

- (1) the warehouse facility and grounds;
- (2) products stored in the warehouse;
- (3) equipment; and,
- (4) records pertaining to shipment or receipt of food in interstate commerce.

At the beginning of every inspection, the investigator is re-

quired to show you his or her credentials to verify that he or she is an FDA employee and give you an official notice of inspection. This lets you know that his or her inspection is authorized by Federal law. At the end of the inspection, the investigator will leave a written report of the objectionable conditions that he or she observed. Refusal to permit an FDA investigator to enter a warehouse to make an inspection is a violation of the law. We are given this authority by Section 704 of the Federal Food, Drug, and Cosmetic Act.

During this inspection, the investigator may collect samples of food products that he or she suspects may be contaminated or misbranded. When samples are taken, the investigator is authorized to pay you the current market price and is required to give you a written receipt for the samples.

FDA has established guidelines regarding the size of samples collected. The size is affected by the type of product, the amount available, the type and amount of contamination observed, and so forth. The sample should be representative of the lot from which taken.

The samples collected during a warehouse inspection are analyzed by our laboratory in Atlanta, Georgia, to determine if the food is contaminated or to confirm elements of filth such as rodent excreta or insects. Now, let's take a closer look at the requirements of the law.

First, it is illegal to store, sell, or offer food products for sale which are adulterated. This applies to any food which is in-

tended for the public. Adulterated or contaminated foods fall into four categories under the law. The categories are:

1. Filthy foods
2. Putrid foods
3. Decomposed foods
4. Foods otherwise unfit for human consumption

These are found in Section 402(a) (3) of the Federal Food, Drug, and Cosmetic Act. There are many means by which food becomes adulterated - and therefore unfit for human consumption. High on the list are rats, mice, and other similar pests. Rats and mice are recognized to be among the most filthy of animals. They destroy and contaminate food, and they spread disease. Rodents contaminate food in a number of ways:

1. By eating the food and causing it to become adulterated by their chewing and gnawing;
2. By leaving their droppings and urine in and around the food; and,
3. By leaving other evidence of their presence, such as hairs.

Insects also rank high in adulterating food products. Insects damage food by tunneling and chewing. Some insects - such as flies, maggots, and roaches - also infect food with serious, disease-causing germs. Evidence of insects may be observed in a warehouse by insects

swarming over the infested product or crawling on infested product bags.

Foods which contain disease-causing germs are adulterated within the meaning of the law. Germs can be transmitted to food by workers who don't follow proper sanitation practices, by improper cleaning of the food and equipment, and a variety of other ways in addition to rodent and insect infestation.

The presence of extraneous material can also render a food adulterated. Examples include dirt, rock, glass, sand, metal fragments, etc.

The Federal Food, Drug, and Cosmetic Act further defines an adulterated food as one which has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have become injurious to health. This is found in Section 402(a) (4) of the Act. This section of the law is saying simply that when food products are prepared, packed, or held (as in your warehouse) under insanitary conditions, the food products are legally considered adulterated. These foods are subject to action under the law - whether or not they are actually adulterated. FDA must prove only that conditions exist that could lead to their adulteration. We are looking at the conditions of the facility rather than the product under this section of the law.

Of special interest in a warehouse is adulteration from chemicals - especially insecticides and rodenticides. The Act classifies a

food as adulterated if it contains any poisonous or deleterious substance which may render it injurious to health - and as I just pointed out, if it is held under conditions which may render it injurious to health. Any careless misuse or storage of toxic chemicals, either by your firm or by an outside exterminator is a matter of grave concern to FDA because of the potential harm to consumers. This is one area of your operation where it is incumbent upon you to know - at all times - what is going on in your warehouse. The responsibility for the safe use of poisonous chemicals rests with you and your firm, and you need to know what your exterminator is using and how he is using it.

Section 301 of the FD&C Act is the basis of all regulatory action taken by FDA. There are 18 prohibited acts listed in Section 301, only a few of which are of particular concern to you.

1. The introduction or delivery for introduction into interstate commerce of any adulterated or misbranded product is prohibited.
2. The adulteration or misbranding of such articles after receipt in interstate commerce is prohibited.
3. The receipt in interstate commerce of adulterated or misbranded product and its delivery for sale or distribution to the public is prohibited. This includes giving it away.

You will note that the term interstate is found in each of the above prohibited acts. The Act defines interstate commerce as commerce between any State or Territory and any point outside that State or Territory. Today, most foods have at some point in manufacture or distribution, moved in interstate commerce.

4. The refusal to permit an FDA official to enter your warehouse to make an inspection during normal working hours is prohibited.
5. The refusal to permit an FDA official to look at or copy your shipping and receiving records is prohibited.

Enforcement of these prohibited acts under the statute essentially takes three forms. First, and perhaps of major importance to industry, is criminal prosecution, supporting penalties of fines and imprisonment. The value of criminal prosecution in achieving compliance with the requirements of the FD&C Act lies chiefly in its deterrent nature. Invoking punishment of this kind is apt to deter the performance of the acts condemned by the law.

The defendant in a criminal prosecution case is subject to specific penalties upon conviction. The penalties which may be imposed differ in the case of first and subsequent offenders and where the act has been committed with the actual intention to defraud or mislead.

The second means of enforcement is the civil remedy of seizure under

libel. The provisions authorizing this step are concerned primarily with the confiscation of the offending food products, and their condemnation and destruction when they are found in violation of the statute. When this enforcement method is used, the penalty of a wrongful action is the forfeiture of the product. The law in these cases is concern not so much with punishment as the protection of the public.

Injunction procedures permit the FDA to attack a number of problems in enforcement not readily accessible under the remedies of seizure and criminal prosecution. It differs from these latter enforcement methods in that it is primarily against the food or against the individual committing the offense. Injunctions are designed to stop the violative activity.

FDA Presented by: Lamar H. Furr,
Compliance Officer, FDA, Atlanta
District, at the Warehouse Sanitation
Workshop at Macon, GA, November
13, 1979.

11

FDA REGULATORY PROCEDURES

As I stated this morning, FDA believes that most public health problems result from ignorance or improper interpretations of the law and not from deliberate avoidance of the law. FDA also takes the position that the firm is responsible for sanitation regardless of the number of consultants, pest control operators, etc., the firm may employ. This does not exclude the consultants and pest control operators from a degree of responsibility - merely that the prime responsibility for maintaining sanitary conditions rests with the firm and its responsible individual or individuals. During warehouse inspections, the FDA investigator determines the person most responsible for the operation of the warehouse. The individuals who are responsible for the operation of a warehouse usually are the top corporate officials. They may also include people such as yourselves--warehouse managers. The investigator determines "WHO" has knowledge of the warehouse operations, "WHO" can order corrections, and "WHO" is in a position to prevent violations from occurring.

Serious consequences can follow from an inspection which discloses violative conditions. It is, therefore, worthwhile to consider FDA's post-inspection procedures and regulatory activities. Each procedure requires the personal attention of top management--that person who can make the needed corrections and who can prevent violations from occurring.

AFTER THE INSPECTION

At the conclusion of an inspection the FDA investigator meets with the highest ranking officials possible. The FD&C Act requires that after completing an inspection, but before leaving the warehouse, the investigator making the inspection must leave with management a written report of any conditions or practices which, in the judgment of the investigator, indicate that any food in the warehouse consists in whole or in part of any filthy, putrid, or decomposed substances, or has been prepared, packed, or held under insanitary conditions whereby the food may have become contami-

nated with filth, or whereby the food may have been rendered injurious to health. The List of Observations - Form FD 483 - is used by FDA for this purpose.

Form FD 483 lists those observed conditions which, in the opinion of the investigator, are violations of Section 402(a)(3) and/or Section 402(a)(4) of the FD&C Act and therefore may cause the food to be adulterated. The listed observations are factual and free of conclusions. These observations are prepared in such a way that they may serve the top management of the warehouse as a guide for corrective action.

Included on the FD 483 are specific observations such as:

- Weeds and trash on the grounds around the exterior of the warehouse.
- Opening of at least one inch below the south door.
- Food products stored directly on the floor and against the walls.
- One rodent gnawed 5/10 lb bale of flour in rear center area of warehouse. This bale plus a 2/25 lb bale in the same area were both stained.
- Live and dead sawtooth grain beetles and cockroach excreta pellets beneath 2 pound and 3 pound bags of rice in south center area of warehouse.

- Pellets of retail insecticides stored adjacent to pellets of retail foodstuffs.
- Four bales of 10/5 lb flour bags in southwest corner. Two of the bales were rodent gnawed; all had fluorescent stains.
- Rodent pellets observed on the floors and shelves throughout the warehouse. At least 300 pellets were present beneath the skid on which 4 bales of 10/5 lb flour bags are stored in northwest corner of warehouse.

The primary purpose of the discussion with management is to call attention to observed practices and conditions which might be illegal. An investigator is instructed not to attempt to play the role of an authoritative consultant. Investigators will not normally recommend specific remedies. They are not construction engineers or pest control operators. However, they are very good at locating sanitation problems.

MANAGEMENT'S RESPONSE

Management response to the observations listed on the FD 483 should be immediate and given during the time the discussion with management is held. Corrective actions or procedural changes which are taken while the investigator is conducting the inspection become a part of the official record of the Establishment Inspection Report which the

investigator must submit. The fact that corrective actions or procedural changes were accomplished immediately and in the presence of the investigator is an indication of management concern. They demonstrate to the investigator and the FDA District Office that you and your firm are paying attention to their observations.

A written response to a FD 483 is not legally required. However, many firms find it desirable to advise FDA in writing of the steps which were taken or will be taken in response to the listed observations. This written response should be in addition to and not instead of an oral response at the time the discussion of the FD 483 items takes place. If your firm sends such a letter, each item listed on the FD 483 and not corrected in the presence of the investigator should be answered as specifically as possible. Indicate what corrective actions or procedural changes have been taken since the inspection. State what new equipment has been purchased, or plant repairs made, or pest control company retained, or new shipping/receiving practices instituted. You might also give any employee training.

The investigator is not the final authority as to whether or not the observed conditions or practices are violations of the FD&C Act. The District Office will review the findings of the investigator and other evidence including laboratory analyses of samples collected. Based on all of the facts, the District Office then determines the compliance status of the warehouse.

If the District Office concludes that no regulatory action of any type is warranted, it classifies the Establishment Inspection Report as "No Action Indicated" or NAI. This classification is issued on the basis of the inspection report review and current guidelines and policy. It indicates that either no action is indicated at this time or the conditions and findings of the inspection do not support the recommendation of the regulatory actions or if they are not corrected would not reasonably result in or lead to conditions that could likely support such actions. Follow-up action to an NAI classification normally is routine reinspection.

A classification of "Official Action Indicated" - OAI - results when an inspection shows that the conditions observed during the inspection, or the combined conditions and the analytical findings, support the recommendation of a regulatory action. A "Voluntary Action Indicated" - VAI - classification occurs when the conditions observed during the inspection, or the combined conditions and analytical findings are not sufficient at this time to support a regulatory action, but if not corrected would reasonably result in or lead to, conditions that could likely support such action.

ADVERSE FINDINGS LETTER

The District Office, after determining the compliance status of a warehouse following an inspection, has available a number of options. These options can include a notice of Adverse Findings Letter, seizure of the product, injunction, or cri-

minal prosecution of the offender. The available options are not mutually exclusive. In other words, a violation of any provisions of the FD&C Act, even if represented by only one shipment, may simultaneously result in a Notice of Adverse Findings Letter being issued, seizure proceedings against the offending product being taken, and criminal prosecution against the responsible individual being instituted. The use of one option does not preclude the use of any other options.

It is FDA's policy that once a violation is uncovered, it should promptly be brought to the attention of management officials responsible for the unlawful practice or condition. Most often this is accomplished by sending to responsible management a Notice of Adverse Findings Letter. This official correspondence, while not considered a regulatory action, indicates FDA's awareness of a violation that must be corrected. When a Notice of Adverse Findings Letter is issued, the Agency has not made a final decision on whether to commence administrative or legal actions.

Each Notice of Adverse Findings Letter is titled "Notice of Adverse Findings." The notice will often specify which section or sections of the law and/or regulations have been violated and will briefly describe the facts establishing the violations. The notice is addressed to management who is believed to be responsible for the violations. A Notice of Adverse Findings Letter is not limited to the observations listed on the FD 483.

A response by management to the Notice of Adverse Findings Letter is expected within a stated period of time - usually thirty days - and must specifically describe each step being taken to effect complete correction of each identified violation. Complete correction includes measures taken to prevent the recurrence of similar violations.

A follow-up inspection may be conducted to determine the adequacy of the promised corrective actions or because of an untimely or unsatisfactory response to a Notice of Adverse Findings Letter. These notices are intended to produce immediate correction. Therefore, they should be given the highest priority.

The enforcement actions of product seizure, injunction, and criminal prosecution are not applied without due consideration. We feel, as you do, that these are serious matters. They rest upon the commission of one or more of a series of acts which the law designates as prohibited acts.

The commission of any of these prohibited acts may subject the offender to criminal prosecution under the statute. In addition, a number of the offenses may justify instituting seizure or injunction proceedings. In a seizure, the shipment itself is proceeded against. An injunction may be instituted to block the channels of interstate commerce to foods that are likely to be violative of the statutory provisions. The choice of enforcement action is not based solely on the appropriateness

of an action for specific violation. Other factors which may contribute to the choice are such things as history of violative practices, failure of other actions to effect correction, hazard to health, and so forth.

SEIZURE ACTIONS

The only proceedings taken against goods that are violative of the statute are seizure actions. The provisions authorizing this step are concerned primarily with the confiscation of the offending food products, and their condemnation and destruction or reconditioning when they are found in violation of the law. When this enforcement method is used, the penalty of a wrongful action is the forfeiture of the product. The law in these cases is concerned with the protection of the public and not so much with punishment.

Seizure actions may be instituted against an individual article or against all food products in a warehouse. This latter type of seizure action is called a mass seizure. It is the procedure which has been used in warehouses where widespread insanitary conditions exist whereby food may have become contaminated with filth, or whereby it may have been rendered injurious to health. Mass seizure can result when samples of multiple lots of food from different parts of the warehouse are found violative.

Seizure of individual articles may be based on their actual contamination or their storage under insanitary conditions.

Seizure is accomplished without the various steps of a formal trial and is directed at the offending shipment. The distribution of this shipment in interstate commerce is halted. If the lot of food which was shipped in interstate commerce is found to be in violation of and prohibited by the FD&C Act, it is condemned. Therefore, it is removed from the channels of interstate commerce. This action of seizure does not necessarily dispose of the matter. As I stated earlier, the same violations may also bring about criminal prosecution against the defendant.

Then what can you do if your food products are seized?

1. You can do nothing whereby within approximately 30 days a Default Decree of Condemnation will be entered which will provide for destruction, donation to charity sale, or disposal of the food as the Court may elect to decree.
2. You may claim the goods--which is a document entered in the Court as a statement of ownership.
3. After a Claim, you have two options.
 - a. If the seized goods can be reconditioned, you would enter a Bond, which is a sum of money held in escrow by the Court pending execution of a Consent Decree of Condemnation. The amount of

Bond is agreed upon among you, FDA, and the U.S. Attorney's office. You would then enter a Consent Decree of Condemnation which is a document filed by you in which you consent that the product seized is in violation as alleged in the Complaint for Forfeiture and is subject to condemnation. It is also a declaration of your intent to provide Bond and to recondition the article under supervision of FDA and to pay costs.

- b. Or if you so desire, you may contest the seizure which could eventually lead to a trial.

In most cases a seizure action will begin with an FDA investigator conducting an inspection of your warehouse. Samples will be collected from violative lots and will be submitted by the investigator to the FDA laboratory for analysis to confirm the violations. If the inspectional and analytical evidence warrants a seizure, such recommendation will be prepared by the FDA District Office and forwarded to our Headquarters Office in Washington for review. If concurred in at that level, a complaint for forfeiture will be forwarded by the United States Attorney. After filing in federal court, an order will be issued by a federal judge directing the U.S. Mar-

shall to go to your firm and seize the violative goods. Seizure may involve the actual removal of your foods from your property or the attachment of the goods by placement of seizure papers. At that time the goods become the property of the court and cannot be removed or manipulated in any fashion under penalty of law.

INJUNCTION

Another form of enforcement used by FDA is an injunction which gives the Food and Drug Administration an effective remedy in blocking the channels of interstate commerce to adulterated or misbranded food.

When would FDA seek an injunction action against your firm? This would occur when you have a history of insanitary problems covering several inspections after you have been told of these problems either by a letter, seizure, or both. Injunctions are also sought by the agency when there is a health hazard involved with your operation.

An injunction action takes top priority over any other regulatory action in movement through the agency and getting to the U.S. Attorney's office. When will you know if the agency is seeking an injunction action against you? You will know when the U.S. Marshall serves you the papers or the U.S. Attorney calls you and so notifies you that an injunction action has been filed against you. What do you do then? I would contact my attorney. This is a very serious action and you are in trouble. Within a short period of time there will probably be a hearing held, and the judge will either grant

the Temporary Restraining Order (TRO) if one is requested by the government or set a date for a hearing in regard to a Preliminary Injunction. If the judge grants a TRO, your firm will be closed for ten days or longer.

There is another option you have. You can enter a Consent Decree of Permanent Injunction which perpetually restrains you from engaging in specified violative practices as indicated in the filed Complaint for Injunction, but this document also provides a means by which you can get back into operation. You are authorized to hire an expert in warehouse sanitation to try to get your firm into compliance so you can resume operation. This decree also states that you will pay FDA's costs in monitoring this injunction action.

Perhaps of major importance to the industry is the enforcement of prohibited acts through criminal prosecution with supporting penalties of fines and imprisonment. Like all criminal prosecutions, the punitive provisions of the FD&C Act are designed to punish offenders and to impress upon them their responsibilities for past violations of the Act. Criminal prosecution may also act as a deterrent to future actions, but it is not necessarily a preventative action.

Before instituting criminal proceedings, the FDA must give the proposed defendant an appropriate notice. Section 305 of the Act provides that the person against whom a criminal proceeding is contemplated under the FD&C Act be given a Notice of Hearing before forwarding such a recommendation to the U.S. Attorney.

This notice may be directed to you and/or your firm. You and your firm are then given an opportunity to present your views, either orally or in writing, explaining why criminal prosecution should not occur.

NOTICE OF HEARING

A Notice of Hearing is issued only when a prosecution recommendation is being considered by the Agency. Attached to the notice will be a Charge Sheet listing the specific conditions, practices, or procedures which FDA views as violations of the FD&C Act. An attached Information Sheet explains the purpose and nature of the hearing, and how the proposed defendant may reply. If a response to the Notice of Hearing has not been received on or before the date set, or a reasonable extension of time has not been arranged, the decision on whether to refer the charges to the Department of Justice for prosecution will be based on the evidence on hand.

The hearing is an opportunity for you to present evidence, offer explanations of extenuating circumstances, and call attention to all changes that have been made in the warehouse. Although corrections after violations may not alter the decision to prosecute, all evidence will be considered. This is your opportunity to present the other side of the story concerning the Charge Sheet violations.

At the close of the hearing, the hearing officer will dictate a Record of Hearing which sets forth all of the points made at the hearing. Documents and other evidence which have been brought to the hearing can be

included in the record. An opportunity will be given to review the record and make suggestions for corrections and additions.

FDA reviews its evidence of the violations and total Record of Hearing. The Agency then decides whether or not to recommend a prosecution.

The defendant in a criminal prosecution case is subject to specific penalties upon conviction. The penalties which may be imposed differ in the case of first and subsequent offenders and where the act has been committed with the actual intention to defraud or mislead.

Under the FD&C Act, a person convicted of a violation of the statute is, as a first offender, liable to imprisonment for not more than one year, or a fine of not more than \$1,000, or both on each count or proven violation. This misdemeanor penalty may be imposed if the offense was committed without the intent to defraud or mislead. But where the defendant has previously been convicted of an offense under the FD&C Act, the period of imprisonment may be increased to three years and the fine to \$10,000 on each count.

Another penalty deals with violations committed with intent to defraud or mislead. Such an offender is subject to imprisonment for not more than three years, or a fine of \$10,000 or both imprisonment and fine for each offense. This penalty affects the sentences of offenders under the law who have acted deliberately and intentionally.

In summary, FDA investigators make periodic inspections of food storage warehouses. The FDA investigators report facts concerning the firm's operations. Based on these facts and laboratory analyses of samples, we may or may not have to institute some of the procedures I have just discussed. The best way to operate is in accordance with FDA's current good manufacturing practice regulations and the State requirements in order to assure that the foods in your warehouse are not adulterated or misbranded.

We would much prefer to see the warehousing industry and all the other regulated industries achieve voluntary compliance with the law. The great majority of the firms we do inspect do achieve compliance and operate with the intention of complying with all aspects of the law.

FDA Presented by: Lamar H. Furr,
Compliance Officer, Atlanta District,
at Warehouse Sanitation Workshop,
Macon, GA, November 13, 1979

FDA INSPECTIONS APPROACH AND IDENTIFIED PROBLEMS

I will discuss FDA's approach to inspecting a food storage warehouse. However, in order for you to understand completely our methods and procedures, it will be necessary for me to touch briefly upon the following points:

- (1) Our objective.
- (2) Review of the legal reasons for the way we conduct inspections.
- (3) Sanitation criteria generally checked by FDA investigators; and,
- (4) How inspectional evidence is developed.

OBJECTIVE: CONSUMER PROTECTION

Simply stated, the objective of our inspections is consumer protection. FDA uses establishment inspections as the basic tool for determining compliance with the Federal Food, Drug, and Cosmetic Act. This does not mean that we evaluate sanitation every time we visit your firm. We may visit for a host of equally good reasons. For example, we may visit:

- (1) To conduct a net weight survey.
- (2) To investigate a complaint which requires examining one or more lots of canned food; or,
- (3) To collect a sample at the request of another FDA District Office.

To completely satisfy your curiosity as to why we are at your firm, ask us, or better yet, accompany us during the visit. All of us can benefit from viewing operations through a different set of eyes. We encourage participation of firm personnel when we conduct inspections.

LEGAL REASONS FOR INSPECTIONS

Earlier today, we discussed the Federal Food, Drug, and Cosmetic Act. I think it is important to reiterate certain portions of that Act.

From a legal standpoint, our investigators are generally checking for two specific prohibitive Acts. One is 301(A), which concerns the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded product. The second is 301(K), which concerns the receiving of a product in interstate commerce and the holding of such a product in a manner so as to cause it to become adulterated.

Sound evidence is required to determine which prohibitive Act has been violated when we find an adulterated lot of food in your warehouse. The mere finding of such lots is not enough, since we may be documenting a manufacturing or shipping rather than a warehousing violation. Therefore, if we find the lot was apparently adulterated at your warehouse, we will attempt to prove that the product was received from outside the state of Florida; was free of contamination when received, and that insanitary conditions existed in the warehouse which were conducive to contamination of the product.

I used the word "adulterated." What does the term mean? A part of our Act defines food to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. This simply means that the food has been contaminated or is otherwise unwholesome.

A second definition which strikes at the heart of our inspection is one that you must fully understand. This second definition in the Act defines a food as adulterated if it has been "prepared, packed, or held (and I emphasize held) under insanitary conditions where it may have become contaminated with filth." This means we may take seizure action against a lot merely because it is being held by you under conditions which might result in it becoming contaminated.

In summary, these sections of the Act should tell us that FDA inspections are conducted to determine several points, including:

- (1) Are violative (adulterated) lots being stored on the premises?
- (2) If so, who is responsible for the violation?
- (3) Are the contaminated lots received from outside the state of Florida?
- (4) Are they held for sale?
- (5) Finally, and importantly, are any products being stored under conditions whereby they may be expected to become contaminated? If the answer is yes, our investigators

may document violations that lead to your entire warehouse being recommended for seizure action.

THE INSPECTION

Inspections are assigned on a bi-monthly basis according to a set of priorities. These include:

- (1) The nature and extent of violations found during the last inspection.
- (2) The number of violations found during the last inspection.
- (3) How long it has been since the last inspection.

Our investigators start their activities by reviewing your firm's factory file. This review is made to alert them of any past problems and where such problems existed in the warehouse. He or she will also review what is stated about management's past attitude and whether any products are manufactured or repacked.

The inspection begins as the investigator approaches your firm. Technically, the inspection has not started, but he or she will obviously be positively or negatively impressed by the environment surrounding your firm.

The inspection actually begins with the issuance of A Notice of Inspection and the displaying of the investigator's credentials to the owner, operator, or agent currently in charge. We ask to see the most responsible individual currently on

the premises and issue the notice to that person. Having met these two requirements of the agency in our Act, we are now ready to conduct the inspection.

We generally obtain limited information on the current status of your firm's operation and will make a short tour of the entire warehouse. The purpose of the initial tour is to determine the plant layout, plan the inspection, and determine if there are readily visible conditions that indicate poor sanitation practices exist. As with the impression formed when entering your firm, the investigator will be positively or negatively impressed by what he or she sees during the first few minutes in your warehouse. If potential trouble spots are found, the investigator will probably take notes of these areas and cover them in-depth at a later time.

- Are storage practices sloppy - as indicated by broken containers, spillage, haphazard storage - all of which contribute to possible infestation.

At this point, most experienced investigators have a good idea of what to expect. A fairly cursory examination will reveal whether or not an extensive infestation is present. For example:

- If goods are stored away from the walls, an inspector can easily detect fresh signs of rodent droppings, usually found first along outer walls where rodents travel; in out of the way patterns.
- If bird droppings appear on window sills.

INSECT ACTIVITY

This is probably the most difficult for the untrained individual to detect. It is easy to recognize once you have seen the various typical forms, usually in more out of the way places and often requires the breaking down of lots. Our experience has been to concentrate on old dirty, unrotated lots.

WHAT TO LOOK FOR

- Live insects and larvae in bag seams, in bottom of cartons, on pallets and floor.

Some of the things the inspector will check are:

- (1) The environment immediately around your warehouse and the structural fitness of the building. Generally, these two points and your actual storage practices reflect management's view of sanitation.

When checking the warehouse environment, we are looking for possible rodent harborage areas such as old pallets, junk, high weeds, rodent tunnels or burrows in the ground, possible entryways into the building, such as broken windows, open and ill-fitting doors, structural defects, etc.

- (2) Storage practices inside the warehouse are evaluated and the investigator will quickly note if:

- Goods are stored in a crowded manner, directly on the floor and against the walls making inspection and pest control nearly impossible (and more suspect).
- Or if goods are stored on pallets - off the floor and away from the walls in an organized manner.
- We use 20, 30, and 40 mesh sieves to isolate insects depending on the product and insect types.
- Insect drilled holes are easy to detect in paper or cardboard.

RODENTICIDE/CHEMICAL CONTAMINATION

- During the inspection, our investigators are constantly alert for possible misuse of pesticides and other chemicals that could possibly cause food contamination. We are suspicious of and would sample any powders spread indiscriminately around the warehouse - DDT tracking powders?
- Pesticide spillage.
- Any designated "morgue" or "distressed merchandise area" will be evaluated since many times it is a focal point for rodent and insect

activity. If bagged animal feeds are not adequately segregated from products such as flour, beans, or cereal, we will possibly check a few of these lots of food. Freezers and cold storage areas will be checked for signs of rodent activity and proper working order. Temperatures will probably be checked to see if refrigerators are being maintained at or below 45° F., and freezers at or below 0° F. Obviously, any evidence of thawing or molding of refrigerated or frozen foods may lead to samples being collected for decomposition or other analysis.

- o Do not be misled into thinking refrigerated foods can't become contaminated by rodents.

Other things we would normally examine, even in an apparently clean warehouse, include:

- (1) Your firm's procedures for examining incoming foods for signs of contamination.
- (2) Stock rotation practices.
- (3) Pesticide usage and schedules.
- (4) Any formalized sanitation schedules.

Of course pets are as objectionable in a warehouse as other pests.

Sampling is an integral part of any inspection where objectionable conditions and/or potential adulteration of foods are encountered. The physical sample itself and any analytical results are limited in the number of facts they represent. The investigator is the principal reporter, who details the conditions encountered during an inspection. By this, I mean that samples and subsequent analytical results must somehow correlate with conditions that were observed and documented by the investigator in field notes, photographs, diagrams, etc.

A good example of conditions which would be a strong fact situation for documenting a 301(K) type of warehouse violation caused by rodents would be the findings of a new rodent nest in a lot of food that had been in the warehouse for several weeks. By the same token, the finding of a dead and well-decomposed rodent in a lot of flour that had only been in your warehouse for several days would be a strong factual situation that some or all rodent defilement found in that particular lot was not caused by your firm.

In any event, the investigator will collect samples documenting adulteration of the lots and record descriptive information which can be reviewed to determine responsibility for the violation.

After determining a lot is possibly or definitely rodent adulterated, the investigator will make notes on the size of the lot, its location, and signs of rodent traffic noted in that area. One or more photographs of the lot will probably be taken, and portions of all of the lot will then

be examined on a bag-by-bag or case-by-case basis. If faced with a large number of defiled bags in one lot, we will usually sample at least six to eight bags exhibiting fluorescent urine stains plus any additional bags exhibiting rodent gnawed areas. We will also collect rodent excreta pellets, rodent hairs, nesting material, or gnawed debris.

Photographs of these specific signs of adulteration will also be taken during the sample collection procedure. Other lots of food stored in close proximity to the previously sampled lot will be checked for signs of similar adulteration. Any signs of rodent activity in the area where a sample was collected will be quantified, written down, and possibly photographed or sampled.

Sampling and documenting adulteration and sanitation practices relative to bird defiled goods is handled in a similar fashion. The exception here is that defilement is generally limited to the upper layers of lots or stored foods, and sampling is generally limited to bags, bales, or cartons exhibiting bird excreta stains. The numbers of live birds and active nesting areas in the warehouse, and particularly in the area where defilement is found, will be counted, recorded in the investigator's notes, and possibly photographed.

Adulteration by insects is one of the easiest types of adulteration to document as being widespread in one or more lots of food products. At the same time, it is by far the hardest type for an investigator to marshal and report facts which can be used to fix responsibility for the adulteration. Perhaps the best example of obtaining facts which would lead to a conclusion of a storage violation is the finding of identical

types of insect activity received from different sources at different times.

The movement of various lots of food out into distribution often precludes our finding this type of fact situation. Instead, we frequently find a lot of flour, beans, or macaroni products which is insect infested, and no signs of other insect activity at all around the lot. For such a lot that has only been in the warehouse a few months, we have only a limited ability to document responsibility for the violation. For this reason, it is not at all uncommon for experienced investigators to carefully examine cracks in floors, window sills, electrical switch boxes, etc. to pinpoint responsibility.

After or while completing collection of samples of adulterated lots, the investigator will document conditions/practices which could reasonably be expected to have caused the lots to have been adulterated while stored at the warehouse. This includes measuring entryways into the building, documenting harborage areas, and documenting storage practices which prevent good stock rotation, and cleaning operations. Essentially, the investigator has now completed the physical aspects of conducting the food warehouse inspection. He or she should have obtained as much factual evidence as possible or necessary to provide proof in a Federal court that a lot or lots of food were defiled or are being held under conditions whereby they may be defiled, and who was responsible for the violations.

Records showing receipts of the lots of food sampled will be reviewed and copied. You might be asked to sign an affidavit attesting to the interstate nature of the goods. I-

identity of persons having knowledge of the receipt and storage of the foods will be obtained. If management of your operation has not been shown the lots exhibiting signs of adulteration, the investigator will probably attempt to point these lots out to responsible individuals. He or she will also probably volunteer to physically point out observed insanitary conditions/practices which, in their judgment, may have led to adulteration of stored foods. Let me reemphasize two important facts which often times management fails to take advantage of:

- (1) Assign a responsible individual to accompany our investigator during the inspection; and,
- (2) Learn new inspectional techniques to assist in identifying potential problem areas.

At the close of the inspection, the owner, operator, or agent in charge will be provided with a receipt for any samples collected (FDA Form 484) and a list of inspectional observations made during the inspection (FDA Form 483). Payment for all samples will be offered regardless of how small the amount.

The list of inspectional observations will identify any conditions or practices noted which in the investigator's judgment, indicates that food being stored is adulterated within the definitions of adulteration I discussed earlier. Our investigators are instructed to discuss the list of inspectional observations in a frank, courteous, and

responsive manner. We may make some very general suggestions and point out sections of the Food, Drug, and Cosmetic Act that may have been violated. They are not authoritative consultants and our comments are usually from the standpoint with what needs to be done rather than how to do it. I urge you to enter into meaningful dialogue with our investigator concerning inspectional findings.

 Presented by: Inspectional Personnel, FDA, Orlando District, at the Warehouse Sanitation Workshop at Miami, FL, November 26, 1979.

FDA INDUSTRY ASSISTANCE

My role as the small business representative is to help small business comply with the Federal food laws and regulations. The exact form of assistance will be determined by the collective and individual needs of your industry and your firms. The assistance could be:

- (1) Conducting more seminars such as this one;
- (2) Participating in meetings that your own local or regional groups may plan;
- (3) Providing educational material;

We have a wide range of educational materials available that you can use in warehouse training programs. We have brochures, posters, slide shows, films, fact sheets, and so forth. My office will be happy to get copies of any materials you need. The assistance would also be a dialogue with you as individuals discussing questions you have about different aspects of the food laws and how they affect your firm.

The better you understand your obligations, the better you will be able to comply with the Federal regulatory requirements. There must be communication. The Small Business Representative serves as the focal point for you for that communication.

To give you an idea of how audio-visuals can benefit you and your employees, we have prepared a slide presentation for use in your own company training program. This slide show which was prepared by the Bureau of Foods' Industry Programs Branch illustrates practices that can be used to resolve sanitation problems. It covers a wide range of areas - pesticides, pests, personal hygiene, and, will be available to you for employee training sessions. I believe it will help you in enlisting employee support and commitment to proper warehouse sanitation. See page 69.

As I said earlier, much of my work will depend on your needs. I trust we can get together and work on programs that will enable you to better understand your obligations under the Federal food laws and regulations and assist you in complying with those requirements.

FDA Presented by: Bradley Eichorst, Small Business Representative, FDA, Atlanta District, at the Warehouse Sanitation Workshop at Lexington, KY, October 22, 1979.

WAREHOUSE SANITATION

ARTICLES



VOLUNTARY INDUSTRY SANITATION GUIDELINES FOR FOOD DISTRIBUTION CENTERS AND WAREHOUSES

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I. Foreword

These guidelines were prepared for receiving, handling, storage, and shipping of food and food products contained in retail and/or shipping containers at food distribution centers and food warehouse establishments, referred to as "food warehouses" throughout these guidelines. The term "food(s)" in these guidelines means foods and food products which are contained in retail and/or shipping containers, but includes items such as fresh produce received unpackaged or in partially open packages, which are subject to various specific additional portions of the guidelines.

The purpose of these guidelines is to promote receiving, handling, storage, and shipping of food and related items at such establishments in a manner that will assure the continued delivery of safe, sanitary, and wholesome foods to consumers.

It is further intended that conscientious adherence to the letter and spirit of these guidelines will not only minimize the chance of noncompliance with applicable governmental requirements for food sanitation, but will improve and maintain the overall effectiveness and quality of the practices by which foods are brought to the American consumer.

In this context, it is essential that management, including those directly responsible for any food warehousing activity, make provision for persons employed in a food handling capacity to receive the degree of training, emphasis, and support commensurate with their job responsibilities and with ensuring the effective implementation of the provisions of this document.

These guidelines, of necessity, are neither exclusive nor all inclusive; they are, however, in-

tended to assist management and food warehouse operators in developing and maintaining facilities, methods, practices, and controls for the receiving, handling, storage, and shipping of foods at the food warehouse establishment in a manner that protects the public health.

They are designed to deal with exposed or otherwise uncovered foods only to the extent that such foods are exposed or uncovered during receiving, handling, storage, and shipping in the food warehouse establishment.

They are not designed to cover food manufacturing, processing, or packaging areas and related equipment, practices, and procedures which are subject to regulations and/or guidelines specifically developed for those types of operations.

If food warehousing and food manufacturing, processing, or packaging operations are maintained in the same establishment, neither type of operation should interfere with the compliance with any good sanitation practices, guidelines, or regulations applicable to the other type or types of operations.

II. Buildings and Grounds

A. *Maintain Grounds Around Food Warehouses in a Sanitary Manner:*

- Maintain the grounds around food warehouse buildings under the control of the operator in a well-drained condition, and free from conditions likely to lead to contamination of foods in the food warehouse, leaving the food warehouse, or being delivered to the food warehouse.

- Keep grounds clean and free of discarded equipment, lumber, litter, waste, refuse, and uncut weeds or grasses within the immediate vicinity of the food warehouse which may provide breeding places or harborage for rodents, insects and other pests.

- Locate outside waste disposal containers on properly drained areas, clean them as needed, and keep them covered between use.

- Maintain and surface driveways, truck aprons, and rail sidings at receiving and shipping areas and parking areas to facilitate good drainage and to minimize dust and dirt being blown or tracked into the food warehouse. Maintain them in a clean, well-drained condition.

- If the food warehouse buildings are closely bordered by grounds not under the operator's control, exercise special care in the food warehouse, by inspection, extermination, or other means, to exclude and control pests, dirt, and other potential contaminants originating from such non-controlled grounds.

B. Maintain and operate food warehouse buildings and structures in a sanitary manner:

- Provide floors and interior walls which are adequately cleanable and keep them clean and in good repair.

- Suspend fixtures, ducts, and pipes which are over working areas so as to prevent drip or condensate from contaminating food or food packages.

- Maintain adequate separation by location or other effective means for those operations which may cause contamination of foods with undesirable chemicals, filth, or other extraneous material.

- Provide adequate lighting to areas where food is received, stored, held or assembled for delivery, in order to facilitate handling, processing, and examination of merchandise and to permit adequate inspection, clean-up, and repair of the buildings and their structures.

- Provide adequate lighting in hand washing areas, dressing and locker rooms (if present), and toilet rooms.

- Employ appropriate special efforts to maintain sanitation whenever necessitated by unique features of structure or design.

- In a food warehouse utilizing light bulbs, light fixtures, skylights or other glass over exposed food, such as produce items in mesh bags, etc., use safety type bulbs or shielded

fixtures to prevent food contamination in case of breakage.

III. Fixtures and Equipment

- Provide food warehouse equipment which is suitable as used and maintained, and is of design, material, and workmanship which permits it to be adequately cleaned and properly maintained by the methods used at the establishment.

- Use and maintain the equipment so as to prevent the adulteration of foods with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

- Install and maintain equipment in a manner which will facilitate its cleaning and the cleaning of adjacent spaces.

IV. Sanitary Facilities

Provide the food warehouse with adequate sanitary facilities and accommodations:

A. Water Supply:

- From an adequate source, provide a water supply which is sufficient for the food warehouse operations.

B. Sewage:

- Dispose of sewage into an adequate sewerage system or through other appropriate means.

C. Plumbing:

- Install and maintain plumbing of adequate capacity and design and in accordance with applicable governmental sanitation requirements, if any, so as to provide sufficient quantities of water to required locations throughout the food warehouse, and to properly convey sewage and liquid disposable waste from the food warehouse.

D. Toilet Facilities:

- Provide toilet facilities which are adequate, kept in good repair, conveniently located, well-ventilated, and in compliance with applicable governmental sanitation requirements, if any.

- Provide them with self-closing doors and with walls, ceilings, and floors which are tight fitting and of a material which can be easily cleaned and kept in good repair; and maintain them in a clean condition.



- Furnish toilet rooms with toilet tissue, and post signs instructing employees to wash their hands with soap or detergent before returning to work.

- If toilet rooms are located near areas in the food warehouse where exposed foods, such as produce items in mesh bags, might be subjected to airborne contamination, provide them with self-closing doors which do not open directly into such areas.

E. Hand Washing Facilities:

- Provide adequate hand washing facilities in the toilet rooms or in places convenient to the toilet rooms for hand washing after use of the toilets.

- Furnish such facilities with hot and cold running water, hand-cleansing soaps or detergents, sanitary towels, or other suitable drying devices.

- Provide adequate receptacles, with covers, for disposal of hand-drying articles or waste material.

- Maintain the washing facilities and the surrounding areas in a clean condition.

F. Dressing and Locker Areas:

- If dressing and locker areas are present, provide them with adequate ventilation and lighting, and maintain them in a clean and orderly condition.

- If lockers are present, provide them with sufficient ventilation to keep them dry for the retardation of mold and odors and maintain them in a clean condition, free from trash, food scraps, or litter which serve as insect or rodent attractants. Keep the tops of such lockers clean, and do not use them as surfaces for the storage of materials.

G. Eating Areas:

- If there are eating areas in the food warehouse, enclose them adequately or locate

them in areas away from operations. Provide adequate space, light, and ventilation in such areas. Clean eating areas regularly, and provide them with a sufficient number of covered receptacles for disposal of meal trash. Clean such trash receptacles regularly and do not permit them to become insect or rodent attractants.

- Clean and inspect vending machines and surrounding areas at regular and frequent intervals to detect and correct conditions of insanitation which may exist in or around such machines.

- If drinking fountains are provided, locate them conveniently and clean them regularly.

V. Sanitary Operations

A. Keep Buildings and Equipment Sanitary:

- Maintain buildings, fixtures, equipment, and other physical facilities of the food warehouse in good repair and in a sanitary condition.

- Conduct cleaning operations in such a manner as to minimize the danger of contamination. For cleaning and sanitizing procedures, utilize detergents, sanitizers and other supplies which are safe and effective for their intended uses.

- Exclusive of packaged products held for distribution, store and use in the food warehouse only such toxic materials as are required for necessary activities, such as for maintaining sanitary and pest free conditions, for use in laboratory testing procedures, or for food warehouse and equipment maintenance and operation. Identify and use such products only in such manner and under such conditions as will be safe for the intended use.

- Use pesticides only under such precautions and restrictions as will prevent the contamination of food and food packaging materials.

B. Rubbish:

- Convey, store, and dispose of rubbish in a

manner which will minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of warehoused food, food containers, ground surfaces, and water supplies.

C. *Pest Control Programs:*

- Establish and maintain positive control programs designed to exclude and eliminate pests from the food warehouse and to deny them harborage, in order to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects).
- Keep trained security dogs out of actual storage areas to avoid excreta contamination of foods stored at floor level. Keep cats out of the food warehouse.
- Implement these programs as an integral part of the construction, maintenance, operational, and personnel programs described elsewhere in the guidelines.

VI. **Procedures and Controls**

Conduct operations in the receiving, inspecting, transporting, handling, segregating, recouping, and storing of foods in accordance with appropriate sanitation principles. Implement overall sanitation under the supervision of an individual assigned responsibility for this function.

Take reasonable precautions, including the following, to assure that food warehouse procedures do not contribute to contamination of foods by harmful chemicals, objectionable odors, or other objectionable materials.

A. *Incoming Product Shipments:*

The integrity of the food warehouse sanitation program requires that the materials, including foods and their packaging, which are received into the warehouse do not expose the food warehouse to contamination by reason of infestation by insects, birds, rodents, or other vermin, or by introduction of filth or other contaminants. It is often useful, when practicable, to work with suppliers and shippers in advance to establish guidelines for acceptance, rejection, and where appropriate, reconditioning of particular product, taking into consideration factors such as the nature, method of shipment, and ownership of the product, in order to facilitate the effective implementation of these programs.

1. Within a reasonable time after arrival of a car or truck, and before product is unloaded, the product should be inspected to the extent permitted by the loading of the vehicle for evidence of damage or of insect or rodent infestation, objectionable odor, or other form of contamination.

Where an adequate inspection has not been possible prior to unloading, further inspect such product during and immediately after unloading.

2. If damaged product has been accepted, keep it separate from other product, and recondition or otherwise handle it as necessary in a manner which will not expose foods or the food warehouse to contamination or infestation.

3. If the inspection reveals evidence of infestation or contamination:

- Determine whether the condition is only "suspect," or is superficial (such as surface infestation of flying insects which may be on, but have not penetrated, soiled, or compromised the integrity of the packaging) and might be fully correctable by fumigation or other means.

- In each such case, remove the product from the food warehouse area, utilizing the vehicle in which it arrived, if feasible, after closing and sealing it.

- In case of contamination, if rejection is appropriate (based on the origin and ownership of the product), promptly notify the carrier and shipper of the time, place, and circumstances of the rejection.

- After removal from the food warehouse because of suspect and/or superficial conditions, concentrated efforts can be made to further evaluate the actual condition of the product, and to recondition it, when possible.

4. Give special attention to product which has previously been rejected, or has otherwise been removed from the food warehouse because of suspect and/or superficial conditions, when it is subsequently received again, to assure that the product and packaging are fully acceptable on reinspection.

5. In the event of serious question, or of failure to agree with the shipper or carrier, as appropriate, as to condition or reconditioning consider requesting evaluation of the suspect or rejected product by appropriate federal, state, or local authorities.



B. *Store Product Properly:*

- Place foods received into the food warehouse for handling or storage in a manner which will facilitate cleaning and the implementation of insect, rodent, and other sanitary controls and will maintain product wholesomeness.

C. *Proper Stock Rotation:*

- Adopt and implement effective procedures to provide stock rotation appropriate to the particular food.

D. *Contaminated or Damaged Foods:*

- Unless promptly and adequately repaired or corrected at or near the point of detection, promptly separate foods which are identified as being damaged or are otherwise suspect from other foods for further inspection, sorting, and disposition.
- Promptly destroy or remove from the food warehouse product determined to present a hazard of contamination to foods in the food warehouse.

E. *Hazardous Non-Food Products:*

- Handle and store non-food products which present hazards of contamination to foods stored in the same food warehouse by reason of undesirable odors, toxicity of contents, or otherwise, in a manner which will keep them from contaminating the foods.
- Take special measures to safeguard from damage and infestation those foods which are particularly susceptible to such risks.

F. *Avoid Damage to Packaging:*

- Exercise care in moving, handling and storing product to avoid damage to packaging which would affect the contents of food packages, would cause spillage, or would otherwise contribute to the creation of insanitary conditions.

G. *Shipping:*

- Prior to loading with foods, inspect rail car and truck and trailer interiors for general cleanliness and for freedom from moisture; from foreign materials which would cause product contamination (such as broken glass, oil, toxic chemicals, etc.) or damage to packaging and contents (such as boards, nails, harmful protrusions, etc.); and from wall, floor, or ceiling defects that could contribute to insanitary conditions.
- Clean, repair, or reject them as necessary to protect foods before loading.
- Exercise care in loading foods to avoid spillage or damage to packaging and contents.
- Maintain docks, rail sidings, truck bays, and driveways free from accumulations of debris and spillage.

H. *Warehouse Temperatures:*

- Maintain warehouse temperatures (particularly for refrigerated and frozen food storage areas) which are in compliance with applicable governmental temperature requirements, if any, for maintaining the wholesomeness of the particular foods received and held in such areas.

I. *Housekeeping, Sanitation and Inspection:*

- Establish a regularly scheduled program of general housekeeping, sanitation, and inspection to maintain floors, walls, fixtures, equipment, and other physical facilities in a state of sanitation sufficient to protect foods from contamination or adulteration, and to prevent waste from becoming an attractant and harborage or breeding place for vermin.
- In addition, develop and implement an effective program and procedure for timely cleanup of any debris and spillage resulting from accidents or other unscheduled occurrences.

J. *Pest Control Measures:*

- Implement pest control measures designed to prevent the entrance of pests, to deny them harborage, and to detect and eliminate them, with such schedules, instructions, and procedures, and by such trained and qualified personnel or professional representatives as may be necessary, based on the nature of the foods and other products handled, the structure and condition of the building and equipment, and the surroundings and environment of the warehouse.
- Monitor traps and bait stations, whether inside or outside of buildings, on a regular basis. Use covered interior bait stations designed, located, or protected to prevent spillage. Where appropriate, use bait stations constructed of moistureproof material.

K. *Pesticides:*

- Use only pesticides with labels showing USDA or EPA registration numbers, and only for the uses specified in the labeling.
- Have them applied only by responsible personnel in accordance with the manufacturer's labeling instructions and in a manner which prevents contamination of foods. While not in use, clearly mark and store pesticides in a secure place apart from foods.

L. *Audit Food Warehouse Sanitation Programs:*

- Establish programs internally and/or through outside consultants for effectively auditing the food warehouse sanitation program.

VII. **Personnel**

A. *Employee Practices:*

- Prohibit employees affected by disease in a communicable form, while carriers of such disease, or while afflicted with boils, sores, infected

wounds, or other abnormal sources of bacterial infection, from working in the food warehouse in capacities in which there is a likelihood of food becoming contaminated, or of disease being transmitted to other persons.

- Prohibit clothing or other personal belongings from being stored and food and beverages from being consumed and tobacco from being used in areas where foods are handled or stored.

- Instruct employees who are working in direct contact with exposed or partially exposed foods, such as produce items in mesh bags, etc., to maintain personal cleanliness and to conform to hygienic practices to avoid contamination of such foods with microorganisms or foreign substances such as human hair, perspiration, cosmetics, tobacco, chemicals, and medicants and, if gloves are used in handling such foods, to use only gloves which are of an impermeable material in handling such foods, and to maintain them in a clean and sanitary condition.

B. *Management Responsibilities:*

- Assign responsibility for the overall food warehouse sanitation program and authority commensurate with this responsibility to persons who, by education, training, and/or experience are able to identify sanitation risks and failures and food contamination hazards.

- Instruct employees in the sanitation and hygienic practices appropriate to their duties and the locations of their work assignments within the food warehouse. Instruct employees to report observations of infestations (such as evidence of rodents, insects or harborages) or construction defects permitting entry or harborage of pests, or other developments of insanitary conditions.

- Execute programs of follow-up and control to ensure that your employees, consultants, and outside services are doing their jobs effectively.



Appendix

This appendix to the Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses has been prepared to assist the food warehouse operator in implementation of Sections (I) through (VII) of the *Guidelines*. Information in this appendix will require adaptation for specific application to your operations.

Since no single document can provide all the information necessary for every situation or specify the only methods for compliance, develop your own appendix or company guidelines to reflect your individual applications in the general areas dealt with in the *Guidelines* and this appendix.

I. Preamble

To ensure product wholesomeness and proper sanitation, the food warehouse sanitation program must have the commitment of top management, must be implemented by operating supervision, and must be supported by the entire food warehouse staff. Preventive sanitation—the performance of inspection, sanitation, building maintenance, and pest control functions designed to prevent insanitation in preference to correcting it—should be an important goal of food warehouse management and of food warehouse operations.

II. Organization and Programs

A program to ensure continued success in safeguarding the wholesomeness of food and in providing good sanitation will ordinarily include:

1. An organizational chart showing chain of authority and responsibility.
2. A flow diagram of receiving, storage, and shipping operations.
3. Regular maintenance schedules.
4. Regular sanitation programs.

5. Regular pest control programs.
6. An effective program of follow-up and control including reports to responsible executive officer(s).

III. Check Points and Additional Guides

1. Grounds:

- Keep nearby grounds free of liquid or solid emissions that could be sources of contamination.
- Prevent grounds from providing conditions for insect or rodent harborage.
- Check paving, drainage, weed, and litter control regularly.
- Stack materials which are stored in the open neatly and away from buildings, and on racks above ground level where feasible.
- "No-vegetation strips" around exterior building walls and at property lines adjacent to properties containing potential harborages are helpful for discovering and discouraging travel by rodents.

2. Buildings:

- Provide separate and sufficient space for placement of equipment and storage of materials necessary for proper operations.
- Separate activities that might cause contamination of stored foods with chemicals, filth, or other harmful material.
- Check structural conditions, pest barriers, repair of windows, screens, and doors continuously.
- Seal and clean floor wall junctions and fill holes and cracks; a painted inspection strip is also recommended.
- Keep offices—including overhead offices—in the food warehouse clean, and do not permit them to become attractants or harborages for insects or vermin. Include them in the pest control program.

- Check false ceilings for harborage of insects and possibly rodents.
- Give basements, attics, elevators, and rail sidings, etc., special attention.

3. Sanitary Operations:

- Keep walls, ceilings and rafters free of soil, insect webbing, mold, and similar materials.
- Do not leave unscreened doors and windows open unnecessarily.
- Do not permit dust to accumulate.
- Keep floors free of product spillage, oil dripage, and buildup in all areas.
- Provide proper trash and refuse storage and removal.
- Store tools and equipment properly.
- Clean and flush floor drains regularly.
- Maintain railroad and truck courts free of debris, and properly patrol them for pest control.
- Keep eating and break areas, locker rooms, etc. clean and orderly. Vending machines are often overlooked: keep them and the areas adjacent to them clean and sanitary. Maintain equipment in a properly functioning condition and do not permit it to serve as a source of sanitation or harborage problems.

4. Receiving and Inspection:

- Inspect the materials which are being received for evidence of damage; insect, bird, rodent, or other vermin infestation; and moisture, odor, or chemical contamination.
- Exclude contaminated materials, including product, pallets, and slip sheets, from the building.
- If damaged merchandise is accepted, segregate it for special handling.
- Make sure that incoming and outgoing vehicles are free of conditions that could contaminate product—no birds, rodents, insects, spillage, or objectionable odor should be evident.
- Code or mark foods received at the receiving point to ensure proper stock rotation.
- To facilitate handling of rejected and suspect product, it is often a good idea to develop procedures with individual shippers, carriers, and/or manufacturers for reinspections, returns, etc.

5. Storage:

- Store products in an orderly manner and so that date codes are visible for proper rotation.
- Generally, it is desirable to stack foods on

pallets or racks (or on slip sheets, where a clamp truck operation is utilized), and away from walls so as to allow for inspection aisles between stacks and walls. Painting inspection aisles in a light color is often helpful in maintaining their effectiveness. Where full inspection aisles are not provided, take special care (such as more frequent inspection, rotation, and removal of product for cleaning) to ensure sanitary, pest free conditions.

- Separate bagged and baled foods to provide visibility between stacks.
- Dispose of contaminated or infested merchandise, or otherwise remove it from the food warehouse promptly.
- Promptly remove damaged merchandise and broken containers from general food storage areas. Handle and process salvageable merchandise separately in an area isolated from general food storage; this area probably will require extra sanitation and pest control attention.
- If salvage operations include the repackaging or other manipulation of exposed foods (other than items such as fresh produce received un-packaged or in partially open packages), conduct such operations in compliance with the food sanitation practices, guidelines, or regulations, such as 21 CFR 128, which are applicable to handling exposed foods.
- Do not intermingle chemicals, including pesticides, with food or food products. Such products are best separated by an aisleway.

6. Pest Control:

- Maintain written schedules, log activity, and monitor traps and bait stations regularly.
- Use covered bait stations which are of such types and so located as to reduce the danger of spillage; and where appropriate, use moisture-proof bait stations.
- Keep the pesticides which are used in the food warehouse securely, and separate from foods. Permit their use only by properly trained personnel. Use only types registered and approved by an appropriate government agency for the intended use.
- Check especially for:
 - rodent burrows in nearby grounds,
 - activity at floor wall junctions and doorways, and
 - insect crawl marks in dust accumulation, especially on overhead pipes, beams,



window sills, around flour, sugar, and pet food storage.

- Where feasible, seal load levelers at docks to prevent trash accumulations and rodent harborage and entry; and clean them frequently.
- Look for insect activity in folds of bagged foods.
- Use black light, supplemented with means for distinguishing other chemicals that fluoresce, to check for rodent urine stains; and use flashlights to check for other evidence of contamination.

7. *Shipping:*

- Make sure that transportation equipment into which food warehouse food is loaded is main-

tained in a sanitary condition comparable to that of the food warehouse.

- Make sure that rail cars, trailers and trucks
 - ... are free of birds, rodents and insects or contamination from them,
 - ... are free of odors, nails, splinters, oil, and grease,
 - ... are free of accumulations of dirt or dunnage, and
 - ... are in good repair and have no holes, cracks, or crevices that could provide entrances or harborages for pests.

8. *Follow-Up:*

- Exercise programs of follow-up and control to ensure that your employees, consultants, and outside services are doing their jobs effectively.



IX. Reprint of Part 110, Title 21 Code of Federal Regulations

Chapter I—Food and Drug Administration

§ 110.10

Subpart C—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING HUMAN FOOD

Subpart A—General Provisions

Sec.

110.1 Current good manufacturing practice.

110.3 Definitions.

110.10 Personnel.

110.19 Exclusions.

Subpart B—Buildings and Facilities

110.20 Plants and grounds.

110.35 Sanitary facilities and controls.

110.37 Sanitary operations.

Subpart C—Equipment

110.40 Equipment and procedures.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

110.80 Processes and controls.

110.99 Natural or unavoidable defects in food for human use that present no health hazard.

AUTHORITY: Secs. 302(a)(4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(4), 371(a)), unless otherwise noted.

SOURCE: 42 FR 14338, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 110.1 Current good manufacturing practice.

The criteria in §§ 110.10, 110.19, 110.20, 110.35, 110.37, 110.40, 110.80, and 110.99 shall apply in determining whether the facilities, methods, practices, and controls used in the manufacture, processing, packing, or holding of food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions.

§ 110.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions shall also apply:

(a) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(b) "Plant" means the building or buildings or parts thereof, used for or in connection with the manufacturing, processing, packaging, labeling, or holding of human food.

(c) "Sanitize" means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other microorganisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

§ 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to assure the following:

(a) *Disease control.* No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.

(b) *Cleanliness.* All persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall:

(1) Wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination of food products.

(2) Wash their hands thoroughly (and sanitize if necessary to prevent contamination by undesirable microorganism) in an adequate hand-washing facility before starting work, after each absence from the work station

§ 110.19

and at any other time when the hands may have become soiled or contaminated.

(3) Remove all insecure jewelry and, during periods where food is manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

(4) If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves should be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

(5) Wear hair nets, headbands, caps, or other effective hair restraints.

(6) Not store clothing or other personal belongings, eat food or drink beverages, or use tobacco in any form in areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.

(7) Take any other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food-protection principles and should be cognizant of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this Part 110 shall be clearly assigned to competent supervisory personnel.

§ 110.19 Exclusions.

The following operations are excluded from coverage under these general regulations; however, the Commissioner will issue special regulations when he believes it necessary to cover these excluded operations: Establishments engaged solely in the harvesting, storage, or distribution of one or

Title 21—Food and Drugs

more raw agricultural commodities, as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated or otherwise processed before being marketed to the consuming public.

Subpart B—Buildings and Facilities

§ 110.20 Plants and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be free from conditions which may result in the contamination of food including, but not limited to, the following:

(1) Improperly stored equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests.

(2) Excessively dusty roads, yards, or parking lots that may constitute a source of contamination in areas where food is exposed.

(3) Inadequately drained areas that may contribute contamination to food products through seepage or foot-borne filth and by providing a breeding place for insects or microorganisms.

If the plant grounds are bordered by grounds not under the operator's control of the kind described in paragraph (a)(1) through (3) of this section, care must be exercised in the plant by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-processing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations and production of safe food. Floors, walls, and ceilings in the plant shall be of such construction as to be adequately cleanable and shall be kept clean and in good repair. Fix-

tures, ducts, and pipes shall not be so suspended over working areas that drip or condensate may contaminate foods, raw materials, or food-contact surfaces. Aisles or working spaces between equipment and between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of food or food-contact surfaces with clothing or personal contact.

(2) Provide separation by partition, location, or other effective means for those operations which may cause contamination of food products with undesirable microorganisms, chemicals, filth, or other extraneous material.

(3) Provide adequate lighting to handwashing areas, dressing and locker rooms, and toilet rooms and to all areas where food or food ingredients are examined, processed, or stored and where equipment and utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.

(4) Provide adequate ventilation or control equipment to minimize odors and noxious fumes or vapors (including steam) in areas where they may contaminate food. Such ventilation or control equipment shall not create conditions that may contribute to food contamination by airborne contaminants.

(5) Provide, where necessary, effective screening or other protection against birds, animals, and vermin (including, but not limited to, insects and rodents).

§ 110.35 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, the following:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts foods or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature and under pressure as

needed shall be provided in all areas where the processing of food, the cleaning of equipment, utensils, or containers, or employee sanitary facilities require.

(b) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(c) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment, or utensils or create an insanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate toilet and associated hand-washing facilities within the plant. Toilet rooms shall be furnished with toilet tissue. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is exposed to airborne contamination, except where alternate means have been taken to prevent such contamination (such as double doors, positive air-flow systems, etc.). Signs shall be posted directing employees to wash their hands with cleaning soap or detergents after using toilet.

(e) *Hand-washing facilities.* Adequate and convenient facilities for hand washing and, where appropriate, hand sanitizing shall be provided at each location in the plant where good sanitary practices require employees to wash or sanitize and dry their hands. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand-cleaning and sanitizing preparations, sanitary towel service or

§ 110.37

suitable drying devices, and, where appropriate, easily cleanable waste receptacles.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces, and water supplies.

§ 110.37 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the plant. These materials shall be identified and used only in such manner and under conditions as will be safe for their intended uses.

(b) *Animal and vermin control.* No animals or birds, other than those essential as raw material, shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues.

(c) *Sanitation of equipment and utensils.* All utensils and product-contact surfaces of equipment shall be cleaned as frequently as necessary to

prevent contamination of food and food products. Nonproduct-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles, and other debris. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) should be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that prevents contamination of food or food-contact surfaces. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and product-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surface may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.

(d) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment and utensils with product-contact surfaces should be stored in such a location and manner that product-contact surfaces are protected from splash, dust, and other contamination.

Subpart C—Equipment

§ 110.40 Equipment and procedures.

(a) *General.* All plant equipment and utensils should be (1) suitable for their intended use, (2) so designed and of such material and workmanship as to be adequately cleanable, and (3) properly maintained. The design, construc-

tion, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(b) *Use of polychlorinated biphenyls in food plants.* Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment and causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Since PCB's are toxic chemicals, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of food. The following special provisions are necessary to preclude accidental PCB contamination of food:

(1) New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's.

(2) On or before September 4, 1973, the management of food plants shall:

(i) Have the heat exchange fluid used in existing equipment or machin-

ery for handling or processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate from the food plant any PCB-containing food-contact surfaces of equipment or utensils and any PCB-containing lubricants for equipment or machinery that is used for handling or processing food.

(iii) Eliminate from the food plant any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (a) its toxicity; (b) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (c) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (d) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to be made on an individual installation and operation basis.

(3) For the purposes of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart D—[Reserved]

Subpart E—Production and Process Controls.

§ 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and

storing of food shall be conducted in accord with adequate sanitation principles. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All reasonable precautions, including the following, shall be taken to assure that production procedures do not contribute contamination such as filth, harmful chemicals, undesirable microorganisms, or any other objectionable material to the processed product:

(a) Raw material and ingredients shall be inspected and segregated as necessary to assure that they are clean, wholesome, and fit for processing into human food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as required to remove soil or other contamination. Water used for washing, rinsing, or conveying of food products shall be of adequate quality, and water shall not be reused for washing, rinsing, or conveying products in a manner that may result in contamination of food products.

(b) Containers and carriers of raw ingredients should be inspected on receipt to assure that their condition has not contributed to the contamination or deterioration of the products.

(c) When ice is used in contact with food products, it shall be made from potable water and shall be used only if it has been manufactured in accordance with adequate standards and stored, transported, and handled in a sanitary manner.

(d) Food-processing areas and equipment used for processing human food should not be used to process nonhuman food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human food.

(e) Processing equipment shall be maintained in a sanitary condition through frequent cleaning including sanitization where indicated. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(f) All food processing, including packaging and storage, should be conducted under such conditions and con-

trols as are necessary to minimize the potential for undesirable bacterial or other microbiological growth, toxin formation, or deterioration or contamination of the processed product or ingredients. This may require careful monitoring of such physical factors as time, temperature, humidity, pressure, flow-rate and such processing operations as freezing, dehydration, heat processing, and refrigeration to assure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of the processed products.

(g) Chemical, microbiological, or extraneous-material testing procedures shall be utilized where necessary to identify sanitation failures or food contamination, and all foods and ingredients that have become contaminated shall be rejected or treated or processed to eliminate the contamination where this may be properly accomplished.

(h) Packaging processes and materials shall not transmit contaminants or objectionable substances to the products, shall conform to any applicable food additive regulation (Parts 170 through 189 of this chapter), and should provide adequate protection from contamination.

(i) Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity should be utilized to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records should be retained for a period of time that exceeds the shelf life of the product, except that they need not be retained more than 2 years.

(j) Storage and transportation of finished products should be under such conditions as will prevent contamination, including development of pathogenic or toxigenic microorganisms, and will protect against undesirable deterioration of the product and the container.

Chapter I—Food and Drug Administration

§ 110.99 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing and/or processing practices, contain natural or unavoidable defects at lower levels that are not hazardous to health. The Food and Drug Administration establishes maximum levels for such defects in foods produced under good manufacturing and/or processing practices and uses these levels for recommending regulatory actions.

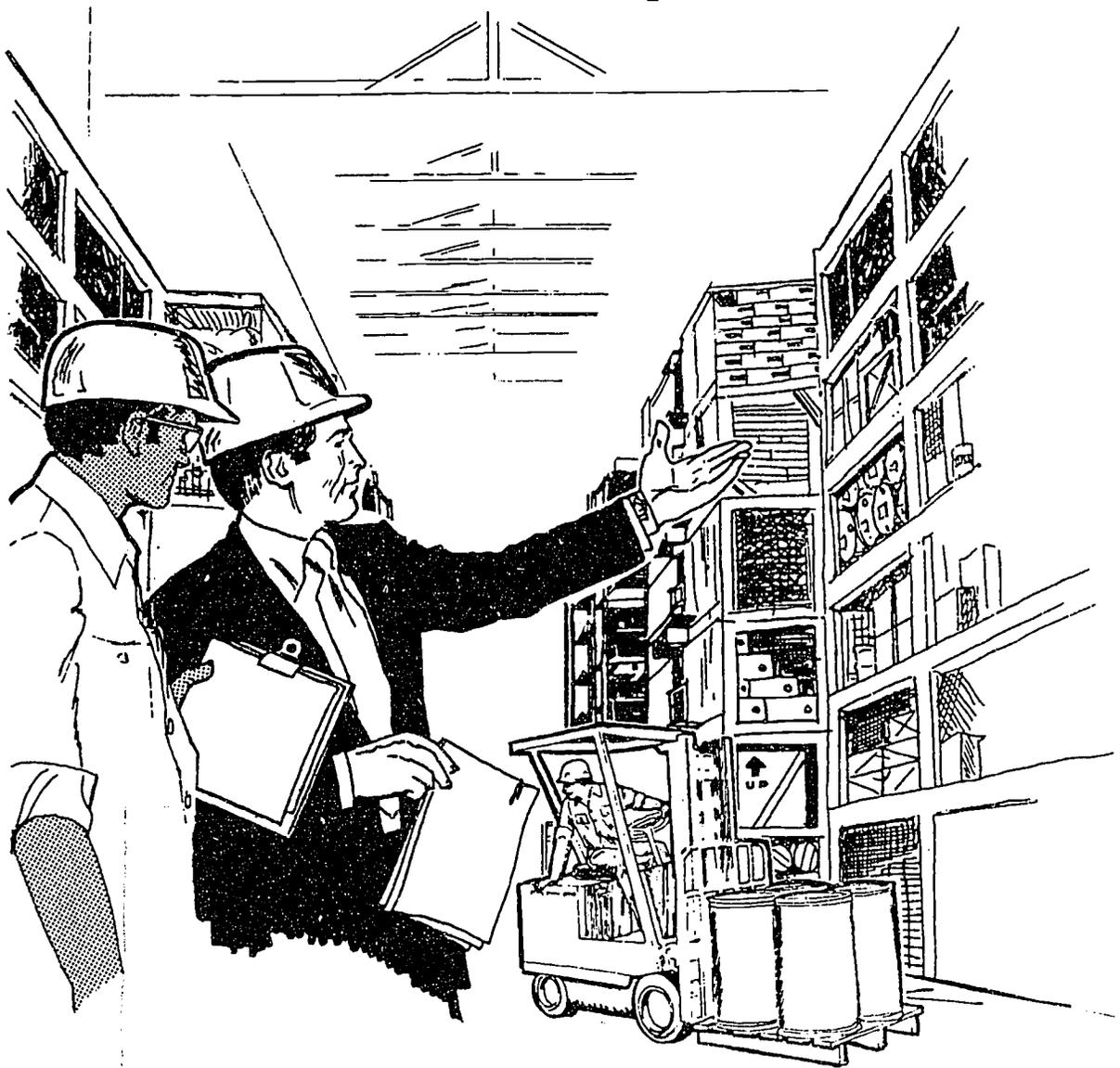
(b) Defect action levels are established for products whenever it is necessary and feasible. Such levels are subject to change upon the development of new technology or the availability of new information.

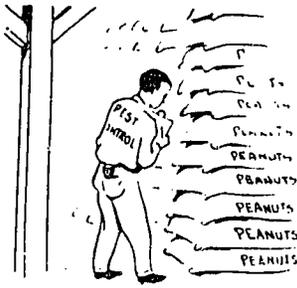
(c) Compliance with defect action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this part that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection indicating such a violation renders the food unlawful, even through the amounts of natural or unavoidable defects are lower than the currently established action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food unlawful regardless of the defect level of the final food.

(e) Current action levels for natural and unavoidable defects in food for human use that present no health hazard are as follows. (Levels that have been adopted on a temporary basis prior to publication as a regulation may be obtained upon request at the Office of the Assistant Commissioner for Public Affairs, Food and Drug Administration, Room 15B-42, 5600 Fishers Lane, Rockville, MD 20857.)

Guidelines for Sanitation Inspection





Sanitation and Inspections

"SANITATION is a way of life." This statement by the National Sanitation Foundation tells the story of the contents of this chapter in just a few words. Sanitation can be good, bad, or indifferent just as anything else. It will usually be as good or as bad as the inclinations of those responsible for it. The desire for good sanitation must be in the minds of those who do the work of achieving it. Various governmental agencies set up regulations for minimum standards of sanitation, but without desire on the part of those who must meet the standards, the level of achievement will be low.

Members of the pest control industry have for many years discussed the role of sanitation as a regular part of their business without arriving at any definite conclusion. Certainly, when a pest control operator is properly qualified, the sale of sanitation consulting services can be a fine and profitable addition to the items he offers to the public. Even though he may not be a technically trained sanitarian, the use of some sanitation techniques can be of value to him and his customers. Each pest control company should decide as a matter of policy for itself whether it wants to offer complete sanitation consulting services to its customers or whether it wants to confine its efforts to advising them on only those obvious points of sanitation which will make the pest control operation easier and more effective.

The information in this chapter will assist you in performing either type of service. The performance of complete sanitation consulting work, however, requires much more knowledge, training and experience than can be included in one chapter. Those who are interested in further study of sanitation should refer to the selected references at the end of this chapter and should, in addition, consult with registered sanitarians in their areas for a more complete understanding of the problems involved.

A sanitarian must have an understanding of the principles involved in many fields such as bacteriology, chemistry, entomology, parasitology, biology, and sanitary engineering. He need not be thoroughly trained in each of these fields, but he must know enough about them to be able to see and understand conditions which could cause trouble.

The most apparent need for good sanitation is in the various food-processing and food-handling industries. Many pest control operators do not have customers who are food processors. All, however, service food-handling accounts such as restaurants, grocery stores, and food warehouses. The sanitation

principles which apply to good food processing also apply to good food handling.

GOVERNMENTAL REGULATION

The Federal Food, Drug and Cosmetic Act includes requirements for sanitary standards of producing and handling food products which are to be shipped in interstate commerce. These requirements are also frequently enforced on state and local levels by health authorities. While many detailed provisions have been written into various health codes, they are all covered by the provisions of the Federal Food, Drug and Cosmetic Act which states that:

"Sec. 402. A food shall be deemed to be adulterated —

1. "If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or
2. "if it bears or contains any added poisonous or added deleterious substance, except a pesticide chemical in or on a raw agricultural commodity, which is unsafe within the meaning of section 406, or if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(2); (the Miller Amendment) or
3. "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or
4. "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or
5. "if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or
6. "if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health."

A sanitarian is concerned with all of these. The pest control operator who is not a sanitarian will most frequently be concerned only with the second provision.

Modern understanding of the words "sanitary" and "sanitation" implies not only conditions pertaining to health, but also the inclusion of anything in a product which does not belong there. This definition would include for example microorganisms which may not be harmful to health, as well as dirt, decomposed but not harmful foods, insect fragments, rodent hairs and excreta, and insecticides.

Modern legal interpretation of the word "adulteration" gives it a broad meaning. The existence of insanitary conditions during preparation or packing or the presence of filth or other extraneous material,

cooked or raw, safe or harmful, visible or invisible, is in violation of the law.

Also, the present law considers food products for human consumption and feed products for animals in the same manner. Regulations which apply to one also apply to the other.

At the time of inspection by any food and drug inspector, the pest control operator, even though he may not be doing sanitation work, may be called on to explain his procedures and to name the chemicals he is using. He should be prepared to explain in detail how and where rodent baits are placed and insecticides applied. He should also know the chemicals he is using and the exact composition of each so he can clear them with the inspector.

THE SANITARIAN

The function of the sanitarian is to help management produce and handle food products so they will be clean, unadulterated and uncontaminated within the full meaning of the law. Because the sanitarian may be held jointly liable with management in case of certain violations, he should be very careful as to the type of contract into which he enters. As a general rule, the consulting sanitarian will not be held liable for the actions of management where the services sold consist entirely of inspections and recommendations to his customer unless his recommendations themselves lead to violations. If the sanitarian also undertakes to train his customer's employees, sell chemicals, or if he performs pest control services himself, he may be liable if his actions cause contamination or contribute to an insanitary product. The agreement should be clear in stating whether the sanitarian is to make his inspections by the usual visual methods or whether he is to provide in addition such services as microscopic examinations, filth tests, and bacteriological examinations. The information in this chapter will be confined to visual inspections because this is the most practical service for a pest control operator to offer. If there are laboratory facilities available, and he has the necessary training, he can offer more.

A sanitation program is rarely effective unless the sanitarian reports to and has the cooperation of top management. Top management is responsible for sanitary conditions whether it engages directly in producing them or delegates the work to others. Every effort should be made to interest top management in concerning itself with sanitation problems. In every food-processing or handling operation definite people should be in charge of and responsible for the effectiveness of the sanitation program. Those who are to carry out the operation should be thoroughly trained in the use of proper tools, chemicals, and techniques to get the job done properly. They must understand that their work is important and that a clean product cannot be produced if their work is not done properly.

THE SANITATION INSPECTION

The sanitation inspection, or survey, is intended to discover anything which might cause or permit contamination or adulteration. It is necessary to consider the product from the time it is first grown or the raw products produced until the finished product is in the hands of the final consumer.

It is obviously impossible in one lesson to include all of the things to be looked for in every inspection. The principles outlined here will, however, apply to

all types of food handling, production, and storage. An inspector must be alert to each new situation he encounters and apply the principles to each case. No amount of detailed instruction will substitute for the good judgment of the inspector.

For purposes of this chapter, we will assume that an inspection is to be made of a food-processing plant. This section will outline a method of procedure and things to look for. The pest control operator can adapt any or all of these items to his operation as he sees fit.

Where and How to Look

There is no specific rule on where to look and where not to look. A sanitarian must observe everything that takes place in every operation he inspects. No place is "private" to the sanitarian. Locked doors and private rooms can contain problems which can affect the entire operation.

It is very important to use a flashlight in making a sanitation inspection, particularly when examining out-of-the-way places. Most exterior dirt and filth can be seen. It is not usually hidden. Many places that an operator would sometimes overlook soon give themselves away by the odor that arises from decaying material. The inspector should reach *under* counters and shelves, and *inside* machinery because various kinds of undesirable materials will often gather here, and can be felt in places that are hidden from visual inspections. Look for the presence of fruit or vinegar flies as these are a certain sign of decaying organic material which is often in an obscure place.

Bacterial and mold growths can frequently be seen on inspection; however, they can always be uncovered by routine laboratory analysis of the products and scrapings from the equipment. A well-equipped food plant will usually have a laboratory which does this work, and when they find excessively high counts, the sanitarian should look very closely for the source.

General Surroundings of the Plant

The inspector should always check to see whether or not the general location of the plant itself may affect sanitation. He should look for such things as *rodent harborages* outside which will feed rats into the building. He should also look to see whether or not such things as *prevailing winds* will bring in flies, dust and smoke from neighboring areas, and whether *soot* from railways may come into the plant. It may be necessary in some situations to keep windows closed in order to prevent such occurrences.

Poor drainage around the plant may cause surface water to run into basements during heavy rains. *Surface water* outside may stand for long periods of time, becoming foul and providing breeding places for insects. In either of these cases, the *slope of the ground* should be changed or drains should be provided so water will drain away from buildings soon after it falls.

Piles of trash, empty containers, old machinery, construction materials and other such items must not be permitted to accumulate because they make good places for rodents and insects to live and breed. *Open dumps* should never be located near the buildings for the same reasons.

Construction and Layout of Buildings

All buildings used in food-handling or processing operations must be well constructed. *Roofs and walls must be tight* so rain cannot enter and wind-blown dust and debris cannot contaminate the product.

Doors should close tightly so rats and mice cannot enter the building, and wherever necessary,

INSPECTION AND SANITATION

both doors and windows should be screened so that flies and other flying insects cannot enter.

Interior construction should be such that it can be cleaned thoroughly and easily. Smooth, tight walls will not provide places for dirt to accumulate or for insects to live and breed. In areas having overhead rafters, check to see if they are being used as runways by rats or mice and also to see if dust and dirt which could fall into the product are accumulating there. Old buildings which have been remodeled into food-handling establishments are especially vulnerable.

The upper side of *overhead piping* should be checked to see that dirt is not accumulating there, and all piping which is likely to sweat must be insulated so that the problem of dripping will not arise.

In any good operation, dust or dirt from bulk handling of raw materials or of finished products must not sift through walls or floors to processing areas where it could contaminate the product. Processing and storage areas should be arranged so it is not necessary to store or move raw materials through processing areas.

Equipment and Machinery

Processing equipment comes in intimate contact with food products being processed. It must, therefore, be constructed so it cannot lead to contamination of the product. All surfaces which come in direct contact with the product must be made of smooth, nonporous materials which will not absorb juices or retain odors. All such surfaces must be easy to reach and to clean.

Each piece of equipment must be built so that it can be cleaned easily because even those surfaces which do not come into direct contact with the product can cause contamination. *Rust and flaking paint* should not be present on any food-processing machinery. Motors and gear boxes should be located so that *no oil drips* onto conveyer belts or into the product. All *frames and braces* should be constructed so they do not provide hidden corners or crevices in which slime or debris can gather.

It is important to make a distinction between operational debris around machinery and debris which has been collecting over a period of time. Spilled material often accumulates on processing machinery and cannot be removed until the end of the working day. This will usually cause no harm. *Debris* which has been gathering over a period of several days is another matter as it creates a growth medium for molds and bacteria. Such debris should be removed as soon as it is found.

Storage and Warehousing

Checking of storage areas for both raw and finished products is just as important as control of the processing areas. As a general rule, *raw materials should be stored in a separate area* from finished goods. Where separate rooms are not available, raw products and finished goods should be kept in different parts of the same room with finished goods being handled with as little traffic through the raw products area as possible.

All materials should be stored in *tightly closed containers* to prevent contamination. Wherever possible, *storage should be on pallets* to protect the contents from moisture and other damage. *Aisles should be left open* so the products can be inspected regularly.

All storage must be *protected from outside dirt* and dust and must not have dirt or moisture falling on it from within the building.

In refrigerated storage areas, all storage should be on pallets with aisles on all sides of the material to permit a *free circulation of cold air*. Air temperatures must be checked periodically to see that they are low enough to protect the products in storage. A special check should be made to see that no mold or rot is developing due to the dampness in these rooms.

In all storage areas rodent and insect control must be good because infestations in storage areas can easily spread to the rest of the plant. *Rodent baits must be safely placed* and must be checked frequently to see that they are fresh and acceptable. Insecticides must be used in such a manner that they *do not contaminate* the products in storage. Where insect infestations are brought in with stored products or where the infestation has developed because the product has been kept in storage too long, it may be necessary to remove and destroy the infested material.

Water Supply

It is most important to *check the water supply* in any food-handling establishment. It is necessary to know whether the supply is from a municipal water plant or from a private source. Water from a municipal source is usually pure and potable so it presents no problem. Where the water supply is private, it is necessary to see that it is checked regularly and adequately for purity by someone who is competent to make such tests.

In some situations water comes from both public and private sources. In such cases it is necessary to be sure that there are *no cross connections* in the piping system so that water from one could contaminate the other.

All water supplies must be checked to see that there is adequate *chlorination*. These checks must be made at a number of points because the chlorine content often diminishes relative to the distance from the source of chlorination. *Pressure* in the water lines *should be maintained* at all times. A check should be made of all plumbing fixtures to see if there is any possibility of *back siphonage* which could draw contaminated materials into the water lines.

Private wells must be examined thoroughly to insure that they are not subject to surface or underground contamination.

When water is supplied from an overhead storage tank, this tank must be protected from the possibility of contamination by birds and climbing rodents. A frequent examination must be made of the inside of the tank to see that no dirt or other debris has gotten into it and that algae are properly controlled.

Sewer Systems

It is necessary to maintain a sanitary sewer system which is *separate from other waste disposal systems* in order to avoid the possibility of toilet sewage backing up into the plant in case of a sewer stoppage. It is important to determine whether sewage disposal is into a municipal or a private system and whether the *system is adequate* to handle the peak loads which will be placed on it.

A thorough check must be made to see that there is *no danger of overflow or leakage* from upper-floor toilets which could drain into storage or production areas. All sewer drains must have *adequate traps* to prevent the entrance of sewer gas or rodents through the drains into the plant. *Sewer lines must be large enough* to carry away rapidly the maximum amount of material which will be put in them.

Waste Disposal

In most instances it is essential to *separate solid wastes from liquid wastes* and only the liquid wastes run down sewer lines. Solid wastes must be removed from the premises frequently so they do not present hazards of odor, molds, decay, or rodent harborages. Whenever possible they should be kept in closed containers until they are removed and these containers must be clearly marked as waste containers so they cannot be used to store food products.

It is necessary to construct the area in which solid wastes are separated and stored in such a way that it can be kept clean and so rodents and insects will not feed or live there. It is best if the separation area has a hard surface, such as blacktop or concrete, and is curbed so liquids will not run off and contaminate surrounding ground.

Eating Facilities for Employees

Good eating facilities for employees are important not only from a sanitation viewpoint but as a matter of morale, and must be large enough to handle the necessary number of people at one time and should be well lighted. Tables and chairs which are clean and in good repair are necessities, and floors should be smooth and kept clean at all times. The entire area must be well ventilated with no unpleasant odors present.

Food displayed in such a manner that it cannot easily be contaminated by people either handling it or breathing upon it will be much less likely to contain undesirable microorganisms. The people who serve food should be trained in good sanitary practices. They should never handle food with their bare hands and should wear clean aprons and proper hair coverings at all times.

Provisions must be made so that foods are not accessible to flying insects. All cream-filled pastries must be kept cold at all times.

Dishwashing equipment must be such that dishes and silverware are thoroughly washed and properly sanitized. Dishes are to be drip dried in a location where they will not become dirty while drying since the use of dish towels is considered to be a very poor practice. After they are clean and dry they must be stored so they will not have dirt or dust accumulate on them.

Worktables, shelves and stoves must be kept clean and free from grease or other food debris.

Refrigerators should be kept spotless both inside and outside so that no undesirable odors are present. Food inside cannot be stacked with one pan on top of another and must be stored loosely enough to permit a free flow of cold air entirely around each container. It is important to locate the refrigerator so that its contents cannot be contaminated by materials carried in from the outside.

Storerooms must be maintained in orderly condition with all food being kept in closed or tightly covered containers to prevent contamination. Old stock should be kept in front or on top of new stock and should be used first.

The food service area should be completely free of any signs of insect or rodent infestation at all times.

Washrooms

Well-ventilated and well-lighted washrooms which are kept clean and dry at all times are a necessary factor in good sanitation. Odors are not only objectionable from the viewpoint of the employees

and indicative of poor sanitary conditions, but are attractive to many insects. Most of the insects which develop in garbage as well as many other pest species find these odors attractive. Handwashing facilities must include hot and cold water, soap, individual towels and conveniently located containers for used towels. Posters must be displayed telling employees they must wash their hands before returning to work areas.

Locker Rooms

Locker rooms must be clean and well ventilated with the lockers made of impervious materials, and kept clean and well ventilated. Showers and sinks must be clean, and adequate hot and cold water must be available. Floors must be kept dry.

Personal Habits of Employees

Employee habits can have a more direct effect on a food product than almost anything else in a plant. Good buildings, sanitary machinery and good processing cannot keep a food product clean unless the employees want cleanliness. Employees must be aware that they are handling food products for human consumption. They should wear clean uniforms and proper hair coverings at all times. Open cuts, sores, or dermatitis on their hands are not permissible. The use of tobacco in any form must be prohibited in any food-handling areas. Spitting must be prohibited at all times.

Employee habits such as carelessly throwing clothes in corners, leaving tools in or on machinery, throwing paper on the floor, and failing to clean up spilled food materials promptly can all lead to contamination of the product. Each crew is responsible for keeping its own area clean during working hours, leaving the heavy cleanup to the regular maintenance crews after hours.

Cleanup Procedure

Each building and the equipment in it is to be cleaned regularly and thoroughly by a well-trained maintenance crew. The method of cleaning must be sufficient to remove hidden as well as visible debris. Where necessary, hot water and detergent must be used. Water and dirt from the floors must not be splashed on processing machinery. All dirt and debris are to be either flushed down the sewer or gathered and removed from the premises regularly.

Rodents and Insects

Visible evidence of insects or rodents in a food plant at any time is not permissible. The inspector should look closely for droppings, runways, grease marks, burrows, nests, and gnawed scraps of food. He must make certain that there is an effective, regular rodent control program being carried out and that the methods and materials being used are safe and cannot possibly contaminate the products. All possible rodent harborages both in and around the plant should be removed.

The inspector is not only responsible for looking closely for any evidence of flies, roaches, ants, stored product pests, and any other insects inside the plant, but also in the area surrounding the plant. If any are present, it is his responsibility to determine where they are coming from and eliminate the source.

Food processing buildings must be properly screened to keep flying insects out. A regular, effective insect control program using safe chemicals in a way which will not contaminate the product is necessary in all cases. All insect and rodent control methods and chemicals must be satisfactory to any governmental

inspector who has jurisdiction over the entire plant.

General Considerations

As mentioned previously, the listed things to be looked for in an inspection are only a small portion of the possibilities which may affect the degree of sanitation in any operation. These are only some of the major items. Details will vary from one plant to another, even in the same type of processing. Used as a guide to a method of thinking, these items can give the inspector an idea of what to look for. Basically, anything or anybody that can have an effect on a product is a proper subject for a sanitation inspection. Anything or any action that could possibly contaminate the product should be corrected.

A large number of the items to be looked for are a matter of housekeeping. Where poor housekeeping exists, there is a good probability that conditions inside the processing lines are not clean and sanitary.

Using the listed items as a guide, the sanitation inspector can fit them to any given situation whether it is a food-manufacturing plant, a restaurant, a grocery store, or any other type of food-handling establishment. The inspection can be extensive or brief, depending on the needs of the customer. It may include all of the operations of the plant or only a portion as necessary. Pest control operators who want to make complete sanitation inspections will find that they must study plant operations, and the various fields applying to them, to do a good job. Others may wish only to use those portions applying to insect and rodent control and make a complete or a very brief report to management for its action.

Inspection Forms

When inspections are to be made on a regular recurring basis, inspection report forms can be used. These may either be general forms to fit a wide variety of types of operation, or may be specific forms made to fill the needs of an individual customer.

General forms should include all necessary main headings together with specific things to look for. Specific forms are usually much more detailed. They can be made out for each total operation or can be divided so individual portions of the operation can be reported separately.

All forms can be made either to show whether the individual sanitation items inspected are satisfactory or unsatisfactory or can be made to grade each item by a number system with one end of the number scale indicating the highest standards and the other the lowest.

Inspection forms are intended as a guide to make certain the inspector does not overlook certain important items which may affect sanitation. It is impossible to put in all items which may occur, even when the form is specifically made for a certain plant. Space should always be provided for anything which may need correction and which may not be listed on the form. The inspector must always be alert for these additional items. All too often a form is used as though it covered everything which might be encountered; important things which are not listed are overlooked. As was mentioned before, no form or detailed instructions can take the place of the good judgment of the inspector.

Recommendations

It is not sufficient for the sanitary inspector just to report to management what is wrong. It is equally important for him to make sound recommendations

for the correction of any deficiency which is found. In making these recommendations, it is necessary to take several factors into consideration. Recommendations in any food-handling operation should take into account the requirements of any governmental agency which may have jurisdiction so as to prevent the seizure or condemnation of any products or the closing of the business.

Such recommendations must also take into account the manpower and the funds available to carry them out. It is always easy to recommend the purchase of new machinery, that stainless steel be used to replace wood or iron, or that concrete buildings be built to replace wooden ones. These things are not always necessary, however, in order to obtain a sanitary condition. If the customer has the manpower, money, and time to make major changes, they are usually best in the long run. Where he does not have these things, it may be necessary for the sanitarian to devise more simple and less expensive measures which will still result in a sanitary operation.

Many sanitarians *take photographs* of points of poor sanitation to include with their reports. This extra effort will pay dividends because it makes it easier for management to see and understand the report, and the necessity for taking corrective measures. As was mentioned previously, many deficiencies in sanitation are simply poor housekeeping. In many instances these deficiencies are only temporary and have been corrected by the time the report is submitted. Photographs make a permanent record of such conditions and can alert management to things which they should be aware of but have not seen.

Pest control operators may not wish to make complete sanitation inspections. Many, however, find it to their advantage to make some recommendations to their customers in order to make their own work easier and more effective. Certainly a warehouse with holes in the walls or loose doors through which rats and mice can enter, a restaurant with uncovered garbage cans outside the back door, a drugstore with a trash room which is not emptied and cleaned regularly, or a business with a trash pile outside, are difficult situations in which to get good insect and rodent control. A pest control operator can help himself, as well as his customer, a great deal if he brings such sanitation shortcomings to the attention of his customer and gets them corrected.

Most customers want clean premises with no insects or rodents. Be sure, when telling a customer about things that need to be corrected, to point out the advantages to him of such action. Try to impress upon him that it is a distinct advantage to him to have you find any irregularities that might occur so that their immediate correction can avoid unfavorable findings by a health official.

In any sanitation program the sanitarian and his customer must work together. The sanitarian must remember that he is on his customer's payroll and is working for him. In many instances it will be necessary to point out to the customer some things which he might not like to hear. To do his job properly, the sanitarian must point out those things which could cause his customer trouble even though the customer or some of his key employees may disagree. It is important that there be a close working arrangement with both sanitarian and customer understanding fully what the other is trying to accomplish. Such mutual understanding can lead to the solution of even the most difficult problem.

INSPECTION TECHNIQUE

In the previous sections of this chapter you have been given a considerable amount of information on sanitation and have learned where to look for irregularities and what many of these irregularities are. We will now briefly consider the subject of how to look for them.

No doubt the basic type of inspection technique is of such simplicity that it defies description. You just point the beam of your flashlight and observe the illuminated area. Unfortunately many inspections are hampered to a great extent because this is the only technique employed. In any food-handling plant and in homes and other buildings as well, there is often a significant number of places which should be inspected that would presuppose the inspector would have developed a certain amount of skill in gymnastics if this method is to be employed. Places such as the lower sides of shelves, pallets, or many pieces of equipment and furniture may be only a few inches above floor level and provide excellent areas of concealment for various pests. The difficulty of performing a casual inspection with a flashlight in such situations is readily apparent.

Whenever you go to the dentist he routinely examines the hard-to-see corners of your mouth by illuminating the oral cavity and examining the image of your teeth in a *small mirror*. This same simple technique of using a mirror can be mastered with very little practice. This method may seem rather farfetched to a person who has never tried it, but a very simple experiment that you can do at home will indicate its usefulness. Stand before a mirror in a darkened room and aim your flashlight over your shoulder at the wall behind you. The image of the lighted wall which you will see in the mirror should be sufficient to show the usefulness of this principle. The application of this technique in practical situations is illustrated in Figure 17-A. A piece of highly polished steel or aluminum can also be used as the reflective surface for this type of inspection. These materials have the advantage of being unbreakable, but the quality of the image which you see may not be quite as good as that reflected in a good mirror.

In many instances valuable information on the status of an infestation can be obtained by examining objects which are either too small to be seen by the naked eye or which are visible but small enough that they are not likely to be noticed in "flashlight inspections." Such things as small fragments of insects and small mites can be collected readily from surfaces upon which they are not observed with ease by means of some variation of the "*swab technique*." The commonly available medical applicator swab consisting of a wad of absorbent cotton wound tightly around a small wooden dowel will serve the purpose quite well. The cotton is moistened with light mineral oil and then lightly wiped across a shelf, baseboard, the underside of a counter or any other surface over which insect pests might pass in going to and from places of concealment. Numerous minute particles can be picked up in this manner and retained for later study using some means of visual magnification. A *hand lens* will be of some value for looking at this material, but if at all possible, it should be viewed through a microscope.

Another variation of this technique is to employ a lightly greased, tissue paper handkerchief to pick up the particles. This has the advantage of covering a wider area per swipe, but it may often

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catch and tear badly if rough surfaces are sampled.

In either case it is necessary to keep each sample separated from the others by some means. Swabs may be kept in small glass or plastic vials, and if this sort of container is employed the swabs can be greased beforehand and placed in clean, capped vials. By preparing them in this way you can avoid having to carry a container of oil on the job. Each vial should be labeled according to the building in which it is taken, the area within the building, and the date of collection. (See Figure 17-B.) When the fragments are subsequently identified, the sites from which fragments were taken can be plotted on a diagram or a sketch of the layout of the building in which they were collected. Such a procedure gives you a visual pattern of the distribution of contaminated areas within the building and can often be quite helpful in showing you where the sources of the infestations might be located.

Another technique which has become popular in some areas for finding certain types of concealed infestations has been borrowed from the family physician. It is sometimes possible to pinpoint the activities of insects such as dry-wood termites and carpenter ants through the use of an ordinary *stethoscope*. The sounds produced by the activities of the concealed insects are picked up and transmitted to your ears in the same manner that the sounds made by the valves of your heart are made audible to your doctor. On occasion this technique may also be helpful in locating cockroach aggregations within wall voids. Although once mastered this technique may be quite useful, it requires a bit of practice and patience to learn to use it properly. It is also limited to specific situations. It is not particularly advisable to wander about at random listening to all surfaces with a stethoscope; your customer might understandably become somewhat alarmed.

One of the useful techniques mentioned in Chapter 8 is that of examining with a *black light* materials which may have been exposed to rodents. If rodent urine is present it will fluoresce when exposed to such light. Another technique, which is sometimes useful when a rodent population is so limited that there may be very few signs of their presence, is to lightly sprinkle a small amount of some fluorescent powder at intervals along suspected runs. A later inspection with a black light should indicate whether or not these powders have been tracked along the run by means of rodent activity.

One of the most valuable and advanced methods of inspection of food-processing establishments is the analysis of samples of packaged foods by means of *microscopic investigation* of extraneous materials extracted from the products. This procedure requires a fairly large investment of funds for laboratory equipment. Most pest control companies are not at present equipped properly to handle such work, but those which are should consider such activities seriously. In the not too distant future this type of service may become an essential part of services rendered by any PCO who wishes to maintain accounts with food processors.

A compilation of standard methods for removal of foreign materials from food products can be found in *Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists*. (The complete bibliographical citation is included at the end of the chapter.) These methods are sometimes rather involved insofar as time and equipment are concerned, but they are of such a nature that a well-

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A series of pictures illustrating steps in the "swob technique"
r fragments and other indications of insect infestation. Upper.
o is passed along the floor in front of a refrigerator. Middle.
places the swab in a vial and corks the vial. Lower. The
is the vial as to site of collection

SCIENTIFIC GUIDE TO PEST CONTROL OPERATIONS

any legal action. It is thus advisable to use only these methods in analyses carried out for your customers. Another reference source which you ought to acquire to aid in the completion of such analyses is Technical Bulletin No. 1 of the U.S. Department of Health, Education and Welfare. (See references listed at the end of the chapter.) The material included therein will be of value to you in the actual identification of the insect fragments and other contaminants extracted.

The use of the above techniques may be of considerable value in making thorough and conscientious inspections, but the most important factor in good inspections lies in your personal approach to the problem. By following a few simple guide lines of procedure you should be able to provide adequate and meaningful inspection service.

First, try to understand what your customer is doing. Learn all that you can about the sort of process being carried out and the sequence of operations which make up the process. Try to analyse the nature of each operation and the equipment used. If this aim can be accomplished, it is sometimes possible to save yourself and your customer considerable time and expense by being able to decide at what step a particular type of contaminant would most likely be introduced into a product and by being able to start your remedial activities at that point.

Second, be aware of any changes which may take place in any phase of the operation from delivery of raw products through the shipment of the finished

article. Sometimes a seemingly minor change may be introduced which may seriously jeopardize the status of sanitation and pest control operations.

Third, keep good records. The records which you keep can be extremely valuable to you and your customer in any number of situations. They may also serve as additional protection should any sort of misunderstanding arise with regard to regulatory officials.

Fourth, be completely honest with yourself. Sanitation and pest control are both broad areas of endeavor which are becoming increasingly complicated from day to day. The combination of the 2 activities is most desirable, but most of us are not as fully and adequately prepared in one as in the other. It is very easy to try to overextend yourself and find later, to the sorrow of both you and your customer, that you have not been properly prepared. Never stop trying to learn more about new areas of endeavor, but be careful to remain within the framework of your qualifications as you proceed.

Selected References

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- Parker, Milton E. 1948. Food plant sanitation. McGraw-Hill Book Co., New York. 447 pp., illus.
- Traux, D. L., ed. 1952. Sanitation for the food-preservation industries. McGraw-Hill Book Co., New York. 284 pp., illus.

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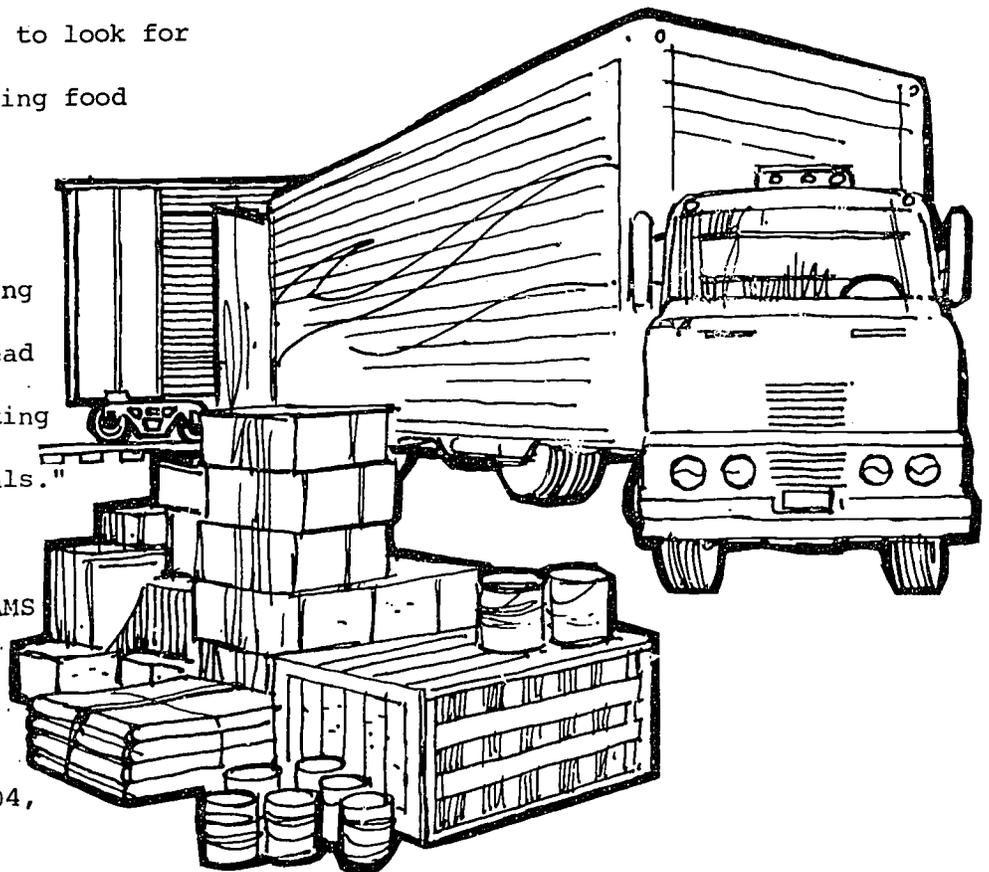
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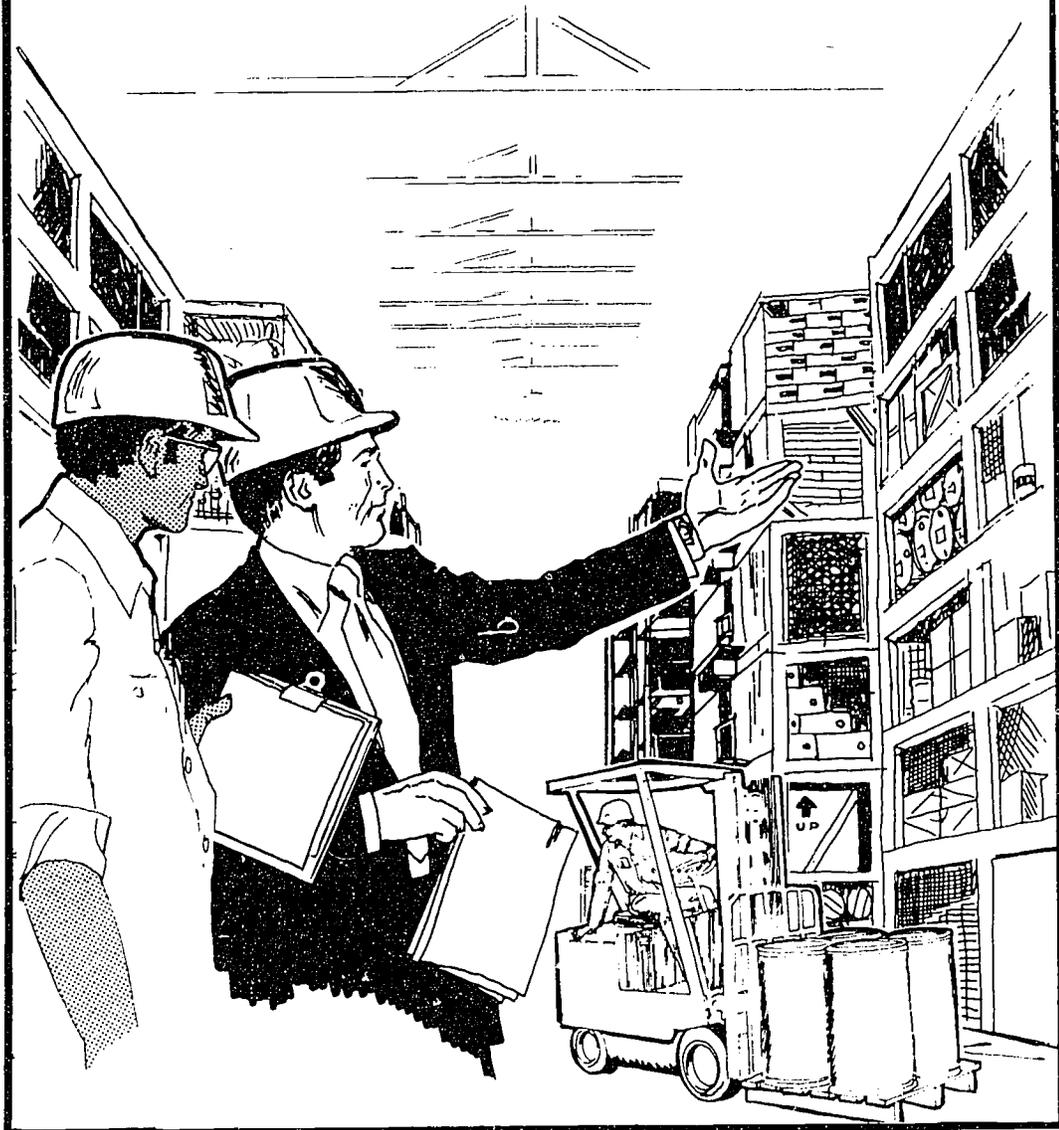
1. Promote personal cleanliness among employees.
2. Provide proper toilet and hand-washing facilities.
3. Adopt "good housekeeping" practices.
4. Keep food handling equipment clean.
5. Reject all incoming contaminated foods.
6. Maintain proper storage temperature.
7. Store foods away from walls.
8. Rotate stock and destroy spoiled foods.
9. Do not use or store poisonous chemicals near foods.
10. Maintain an effective pest control program.



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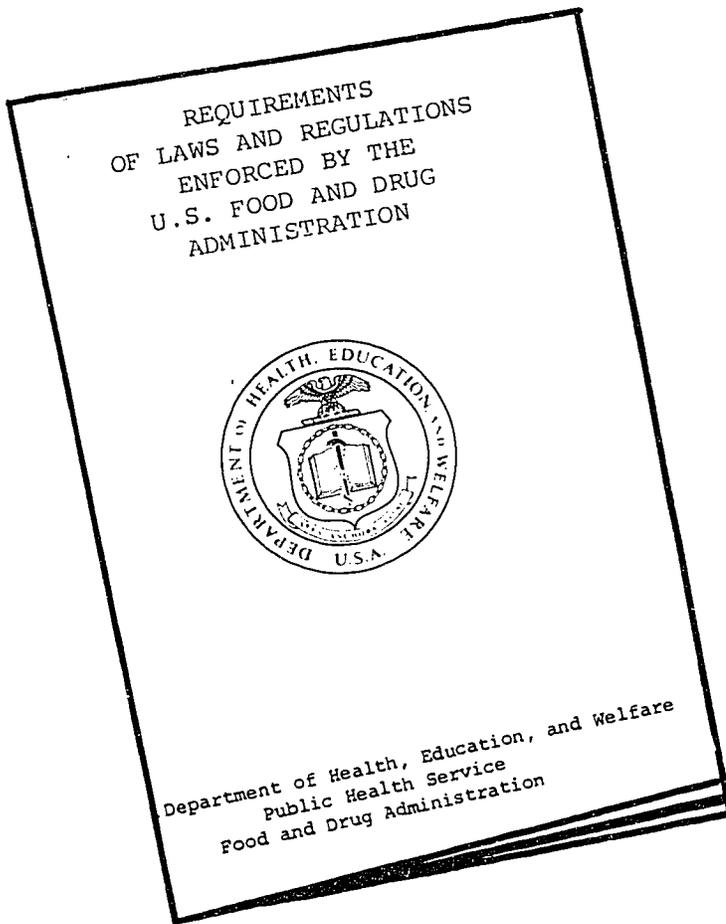
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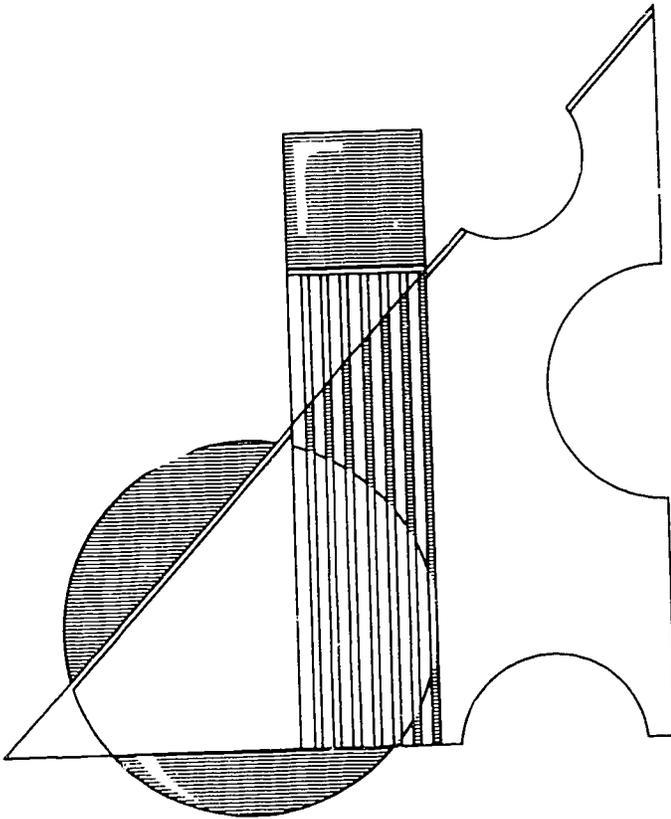
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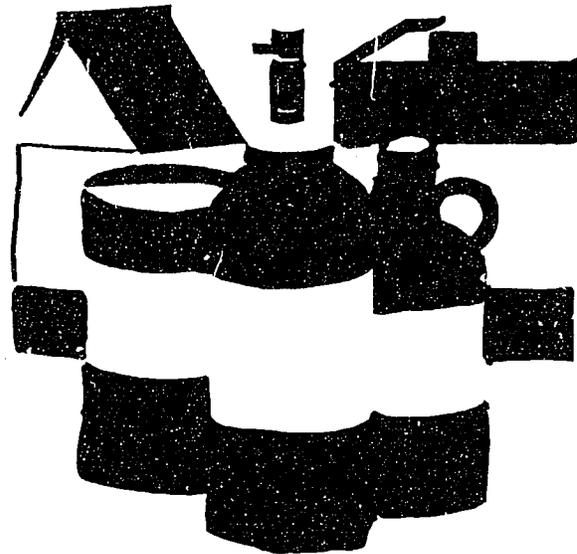


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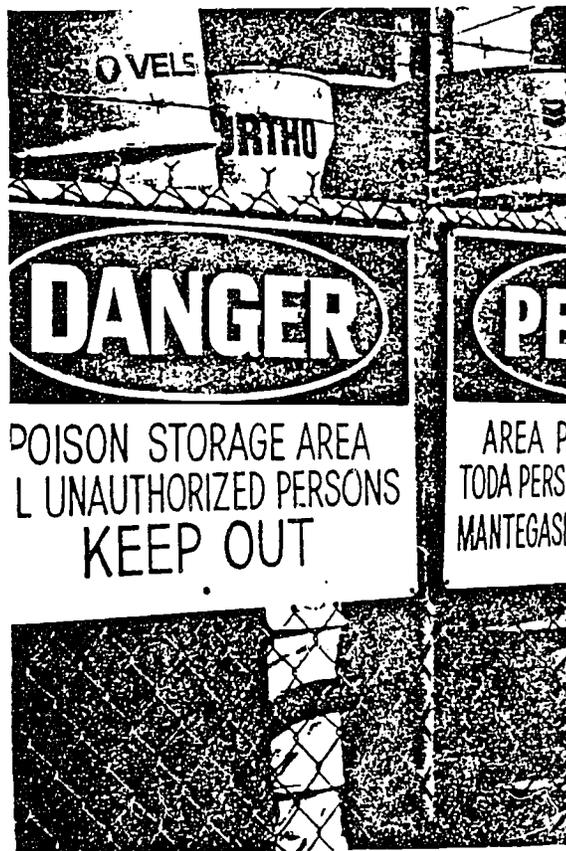


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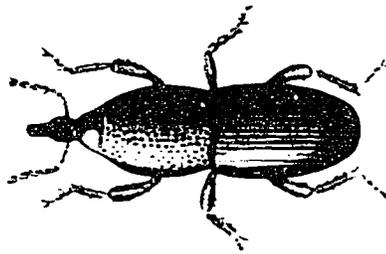
Title 21, Code of Federal Regulations is updated on April 1st of each year. The 1980 edition contains eight volumes applicable to FDA and may be purchased singly or as a set. A description of each volume and its cost is:

- Part 1 to 99. Price \$6.00. General regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. Color Additives.
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