

Sanitation and the Food and Drug Administration

Presented by PHILIP DECAMP

The author outlines the role of the Food and Drug Administration in Food Marketing.

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The Federal Food, Drug, and Cosmetic Act applies to articles in interstate commerce and to imports.¹ The sanitation safeguards of the Federal Food, Drug, and Cosmetic Act state that:

A food or drug is illegal if it is filthy, putrid or decomposed (402(a)(3)).

A food or drug is illegal if it is prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth (402(a)(4)).

A food is illegal if it is the product of a diseased animal or one that has died otherwise than by slaughter (402(a)(5)).

The Food, Drug, and Cosmetic Act is often referred to by the public as the "Pure Food and Drug Act", thus emphasizing one of its basic purposes — the protection of the consuming public from articles that may be deleterious, that are unclean or decomposed, or have been exposed to insanitary conditions that may contaminate the article with filth or may render it injurious to health.

The cleanliness and wholesomeness of foods, drugs, and cosmetics, and the sanitary conditions of establishments in which they are produced, have improved tremendously in recent years. Manufacturers have grown more aware of their responsibility to use clean, safe, raw materials and to process them under sanitary conditions. This responsibility has become an important part of product quality control.

The Food, Drug, and Cosmetic Act is a regulatory law designed for public protection. It provides rules of conduct for food and drug manufacturers just as local ordinances lay down the rules of ordinary daily conduct. The act is a broad act with broad aims, and in enforcement operations the Food and Drug Administration gauges the levels of practical, reasonable compliance not by a set of sharply precise "Do's and Don'ts" but

by a concept of what is or is not "good commercial practice." Good commercial practice is a concept that may vary from industry to industry, from year to year, and with commercial conditions.

In keeping with this concept of current good industry practice, Food and Drug Administration published a set of "Good Manufacturing Practices" guidelines for the food industry in general on December 20, 1968. Under these so-called "umbrella" regulations — which apply to practically all operations where food is manufactured, processed or repacked — the care and handling of food for human consumption is discussed in some rather specific terms. These guidelines are published in the Federal Register and, by now, should be familiar to all concerned with food handling. The highlights of these GMP guidelines tell much of what concerns FDA and a brief look at some of these main points will help you to see exactly what a Food and Drug Inspector looks for and how he approaches an inspection.

In actual practice the inspection starts with a survey of the adjacent premises. Refuse piles, raw materials awaiting processing, and pools of stagnant water, all furnish breeding spots for insects. Sewer outfalls may be in position to pollute the water supply. Dilapidated out-buildings and receiving docks, vacant and abandoned shacks, and litter and rubbish heaps, all afford harborages for rats. These are elements which singly or together will lower the level of sanitation in the establishment.

While it is hardly possible to state categorically that nearby dwellings are a menace to plant sanitation, the nature of these dwellings and their capacity to attract dogs, cats, and stray children to roam at will through the plant are matters for appraisal. If the inspection discloses that dwellings are a menace to sanitation, the report should show clearly the way in which pollution occurs.

The importance of plant construction is determined by the likelihood of rat infestation or the difficulty of proper cleaning. However, it is a basic precept in food sanitation that clean products can be produced with clean methods in an old and difficult-to-maintain building whereas beautiful buildings are totally without value when insanitary procedures are followed. Perhaps the greatest matter of concern should be the arrangement of equipment and installations to permit proper cleaning, and the provisions for screening and rat-proofing.

Adequate light and sanitation are required by all sanitary codes. Just how much light and fresh air are

adequate for the comfort and well-being of employees and are needed for product sanitation is a question for specialists. By sanitary criteria the amount of light provided should be adequate for sorting out unfit materials and doing a clean job. Apart from the psychological and human physiological aspects, sufficient exchange of air should be maintained to dry out damp areas and thus check moldiness and the development of insect pests. Actually, lack of light and fresh air does not directly establish insanitary conditions. As items in a report they are worthy of note for the effect they have on the operations of the plant.

There is no excuse for using polluted water in food establishment. Bacteriological tests for pollution are simple; consulting laboratories ordinarily will make them for a reasonable fee or local health agencies may be able to render such service. Except in rare instances, it may be assumed that a city water supply and ice manufactured from it are free from pollution.

Waste disposal is definitely an important factor in sanitation. Improper disposal may create merely an unsightly and bad-smelling nuisance. It is more likely to create a breeding place for rats and vermin. Obviously in the operation of some food establishments — for example, any canning operation — waste will unavoidably accumulate. The waste disposal problem must be viewed practically and appraised by giving due weight to the probability or improbability of pollution or contamination. Certainly when the refuse pile putrefies or ferments, breeds flies, or serves as a harborage and food reservoir for rats, it must be given a high rating as an insanitary factor.

It is axiomatic that only fresh, sound, clean raw materials should be used in the preparation of food products. This is the first, and a most important, line of defense in preventing the distribution of filthy or decomposed foods. Microorganisms, including bacteria, yeasts, and molds, ferment and rot raw materials of all kinds in the field, in storage, or during transportation to the food processing plant. Such organisms are so widely distributed that, in dealing with food products, they must always be assumed to be present, and food handling measures must be based upon that assumption. Insect pests and rodents may eat, pollute, or otherwise defile vast quantities of natural or manufactured raw materials. Unclean methods of handling and exposure of raw materials may result in contamination with various forms of filth or with microorganisms dangerous to health.

Dirty utensils and equipment reflect a letdown in sanitary control. Some discretion is necessary in citing these sources of filth: pans and buckets with loose seams containing food residues, wooden equipment, soiled towels, and wash clothes. Certainly their use is to be decried; in the manufacture of some products they are important vectors of bacteria which, on laboratory examination, serve to condemn the product.

Generally the disclosure of improperly cleaned equipment is a warning sign toward more direct evidence of filth. Whether or not utensils are dirty obviously depends on the facilities for cleaning them, and the full picture of sanitation will show the presence or absence of suitable water supplies and detergents.

Disinfection of equipment usually requires chlorination. This is to be recommended in food plants but not at the expense of thorough cleaning. On the other hand, failure to use chlorine is not itself always a cause for condemnation. Too often hypochlorite solutions are used, like cheap perfume, on surfaces that should be washed. Chlorine has a legitimate use in sanitation but should be applied to clean surfaces and used in effective concentration.

A steam hose is often used to treat heavy metal equipment, and there is no reason to disapprove of the procedure. However, it is worth very little as a disinfecting method, since flowing steam sprayed on cold metal hardly reaches a high enough temperature to have much effect as a germ killer. The best way to keep equipment clean is to wash it frequently and thoroughly, thus reducing to the minimum the numbers of organisms to be destroyed.

Washing facilities rate with toilets as a prime essential for the personal hygiene of workers. There should be enough of them for the needs of the employees and they should be installed in conspicuous locations so that the employee does not have to hunt for a place to wash his hands. Running water, heated if possible, is essential; the barrel or tub into which all employees immerse their hands serves no good purpose. Some form of soap should be provided. The matter of towels gives rise to debate. It is better to have none than to provide the dirty community towel long viewed with disapproval by public health officials. Paper towels, although expensive and apt to be wasted, are consistent with modern sanitation. Because unclean toilets and lack of washing facilities provide definite possibilities for the output of the plant to be polluted, they constitute an important part of the sanitary inspection.

From the beginnings of sanitary control, sporadic efforts have been made to eliminate rats and mice. Nevertheless, it has been estimated that in any given community the rat population equals that of the human inhabitants.

Specific charges in the indictment of the rat as a destroyer and polluter of food are manifold. The rat stands guilty as charged and consequently demands careful attention in any worthwhile sanitary inspection. Accumulations of fresh excreta, gnawings, rat runs, and damaged merchandise provide evidence of the prevalence of these invaders.

Large numbers of flies in a food establishment are two-fold evidence of insanitation. First, they are carriers of filth and infection; secondly, their presence denotes the existence of the putrescent or decaying matter in which they breed — dunghills, unprotected latrines, inadequate waste water or sewage disposal waste piles, natural swamp, stagnant water, or raw-materials breeding areas. The inspection should disclose the source and establish the evidence to show the relationship of flies to contamination of the food by filth.

The human element, although most difficult to control, stands foremost in a sanitary appraisal. Man, en masse, is not clean. Civilization and education have taught decency, but where education lags, insanitary practices continue. In many large-scale operations, food is handled by those who are ignorant of the principles of personal hygiene. It is reasonable to demand that the food handler have clean hands, that he refrain from committing nuisances which spread filth, and that he be conscious that he is preparing substances for human consumption, so that his activities will not defile those products. Medical certificates possessed by employees are no guaranty of good behavior and the inspector should view their possession skeptically until he knows what type of examination led to their issuance and how long they have been held.

If the establishment is strictly a warehouse facility, the inspector will check to see that management is successful in its task, which requires it to:

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 temperatures.
7. Store foods away from walls.
8. Rotate stock and destroy spoiled foods.
9. Refrain from using or storing poisonous chemicals near foods.
10. Maintain an effective pest control program.

From the wide variety of items I have mentioned, it must be evident that FDA is concerned with the cleanliness of foods in the broadest sense, and within these broad concepts much is to be gained by the cooperation of industry and enforcement officials to ensure a judicious and restrained application of legal sanctions accompanied by the industry's awareness of its problems so that solutions can be worked out with a minimum of regulatory constraint.

LITERATURE CITED

- ¹ Material for this address was, for the most part, taken **ad verbatim** from Food and Drug Technical Bulletin No. 1, **Microscopic-Analytical Methods in Food and Drug Control**.