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The content presented in this section is based on a variety of sources.

foodsafety

U.S. Food Safety Regulations

- **Department of Agriculture (USDA)** – meat, poultry, and eggs
- **FDA** – all other foods
- **Department of Commerce** -- seafood
- **Department of Treasury** -- alcohol

Regulations 242

While the primary responsibility for enforcing federal regulations for the safety of the food supply is within the realm of the U.S. Department of Agriculture (FSIS) and the U.S. Department of Health and Human Service's Food and Drug Administration (FDA), there are no less than 12 separate agencies that oversee various aspects of food safety.

U.S. Department of Agriculture

The USDA is responsible for regulating red meat, poultry, and certain egg products. There are four divisions within the USDA that address food safety. These divisions are: Office of Risk Assessment and Cost-Benefit Analysis (ORACBA), Marketing and Regulatory Programs (MRP), Research, Education, and Economics (REE), and Food Safety and Inspection Service (FSIS). The following are key legislation that the USDA enforces.

Federal Meat Inspection Act in 1967. FSIS carries out mandatory inspections of plants that slaughter livestock. Currently, there are more than 75,000 inspectors who must be present at all meat plants while processing. The inspector has the power to withdraw, which stops processing operations, condemn foods, and obtain plan records. The agency follows the products throughout processing to assure wholesomeness and proper labeling. Under this Act, cattle, sheep, swine, goats, horses, mules, and other equines are to be visually inspected by a federal inspector before slaughter. The carcasses and organs are subject to a post-mortem inspection including inspections during the preparation of meat products. FSIS also imposes detailed facility, equipment, and sanitation requirements FSIS inspectors are responsible for checking compliance with these requirements. FMIA also lists circumstances under which meat articles will be considered adulterated and unfit for human consumption. FMIA also sets out specific situations in which misbranding occurs, such as use of false or misleading labels, use of an incorrect product name, or lack of a label identifying one food as an imitation of another food. FMIA also contains provisions for both criminal penalties and civil sanctions.

Poultry Products Inspection Act of 1957. FSIS carries out mandatory inspections of plants that slaughter poultry. Poultry is defined to include chickens, turkeys, ducks, geese, and guineas and poultry product is defined as the carcass or part or any product made from poultry. The inspection may include examination of poultry before slaughter to determine if it plainly shows any disease or condition that should cause it to be condemned. This Act also defines adulteration in the same manner as FMIA. There are 12 specific situations in which misbranding occurs with regard to any poultry product. These are identical to those itemized in FMIA. Prior approval of labels to be used with poultry and poultry products is also required, as under FMIA.

Egg Products Inspection Act of 1970. FSIS carries out mandatory inspections of plants that process shell eggs or liquid, dried, or frozen egg products. The agency follows the products throughout processing to assure wholesomeness and proper labeling. This Act makes it illegal to buy, sell, or transport eggs or egg products for use as human food that are not inspected and labeled under the provisions of the ACT. Egg is defined to include eggs of the domesticated chicken, turkey, duck, goose, or guinea. Egg product means any dried, frozen, or liquid eggs with or without added ingredients but does not include products that contain eggs in only a relatively small proportion or which have not historically been considered products of the egg food industry. Adulteration, misbranding/labeling are also addressed.

Voluntary Inspection Program. A processor of exotic animals, such as reindeer, elk, deer, antelope, bison, and water buffalo, may apply for approval as an official exotic animal establishment and if approved, receive (Fee-based) inspection services. A voluntary inspection program for rabbits slaughtered for human food operates in a similar manner.

Department of Health and Human Service

Food and Drug Administration. This agency is responsible for the safety of all other food not regulated by the USDA. Food is defined to include articles used for food or drink for man or animal, chewing gum, and any food components. This mandate covers the inspection of food plants and the establishment of standards for composition, quality, and safety of food and food additives, as well as economic standards to assure consumer confidence in labeling.

There are four divisions within the FDA that address food safety. These divisions are: Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), National Center for Toxicological Research (NCTR), and Office of Regulatory Affairs (ORA).

The FDA also determines the types of food in which an additive can be used; the maximum quantity of the additive that can be used; and the information that must appear on the label. The following are key legislation that the FDA enforces:

Federal Food Drug and Cosmetic Act. FFDC Act prohibits the entry into interstate commerce of adulterated or misbranded food. The term adulterated includes products that are defective, unsafe, filthy or produced under unsanitary conditions. The term misbranded includes statements, designs, or pictures in labeling that are false or misleading, and failure to provide required information in labeling. Compliance with this Act is secured through periodic inspections of facilities and products, analysis of samples, educational activities, and legal proceedings. Adulterated or misbranded products may be voluntarily destroyed or recalled from the market by the shipper or may be seized by U.S. Marshals on orders obtained by the FDA from Federal district courts. While the legal requirements that must be met are the same for imported and domestic products, the enforcement procedures are necessarily different. Imported products regulated by the FDA are subject to inspection at the time of entry through U.S. Customs. Shipments found not to comply with the laws and regulations are subject to detention. They must be brought into compliance, destroyed, or re-exported. The statute permits use without prior agency approval of a substance with a long history of use and if it is considered generally recognized as safe (GRAS). A listing of substances that are generally recognized as safe can be found in 21 CFR Parts 182 (substances generally recognized as safe), 184 (direct food substances affirmed as generally recognized as safe), and 186 (indirect food substances affirmed as generally recognized as safe). This information is available online at:

Food Code. This code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. The Code establishes definitions; sets standards for management and personnel, food operations, and equipment and facilities; and provides for food establishment plan review, permit issuance, inspection, employee restriction, and permit suspension. Individual local, state, and federal governmental jurisdictions are encouraged to adopt the Code as the basis for their regulatory guidelines governing foodservice, retail food stores, and food vending operations.

Low Acid Foods Registration and Process Filing. All commercial processors of heat processed low-acid canned foods and acidified foods are required to register their establishments and file processing

information for all such products with the FDA. This is required for both U.S. establishments and those in other countries that export such food to the U.S. Full text of this requirement can be found in 21 CFR 108, 113, and 114 which are located at:

Another agency within the Department of Health and Human Services that addresses food safety issues is the *Centers for Disease Control and Prevention* (CDC). The CDC is responsible for tracking foodborne illness incidents and outbreaks. For more information about the CDC go to their Web site at: www.cdc.gov

Environmental Protection Agency

There are three divisions within the Environmental Protection Agency (EPA) that address food safety. These divisions are: Office of Prevention, Pesticides, and Toxic Substances (OPPTS), Office of Research and Development (ORD), and Office of Enforcement and Compliance Assistance). The following key legislation is enforced by the EPA:

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Sets pesticide residue tolerances or legal limits on the amount of residue that can be found in or on particular foods. The FDA and USDA enforce those tolerances on their portions of the food supply. Tolerance levels have been set for over 9,000 pesticides.

Department of Commerce

There is one division within the Department of Commerce that addresses food safety. This division is the National Oceanic and Atmospheric Administration (NOAA). This division oversees the management of fisheries in the U.S. and is responsible for seafood quality and grading. NOAA Fisheries operates a voluntary inspection program for fish in conjunction with FDA. In 1995, FDA issued its final rule on HACCP plans that must be in place for seafood processors and a guidance documents that consists of recommendations to aid seafood processors in developing their own HACCP plans. NOAA Fisheries has its own authority for the promulgation of grade standards, inspection, and certification of fish and shellfish.

Department of Treasury

There are two divisions within the Department of Treasury that address food safety. These divisions are: Bureau of Alcohol, Tobacco, and Firearms (BATF) and Customs.

Federal Trade Commission

The Federal Trade Commission (FTC) shares jurisdiction with FDA and USDA over claims made by food manufacturers. In 1954, a memorandum of understanding outlined that the regulation of food advertising would be primarily in the hands of FTC, while FDA would have the primary responsibility of regulating food labeling. The FTC's statutory authority with regard to food advertising is broad. In general, FTC requires that any objective claim made in advertising must be supported by a reasonable basis of substantiation that the advertisers has in its possession at the time the claim is first made.


SOURCE: Looney, J.W., P.G. Crandall, and A.K. Poole. 2001. The Matrix of Food Safety Regulations. *Food Technology* 55(4):60-76.

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Inspections

- Inspections can be performed *any* time the operation is open.
- Locate a copy of your previous inspection report.
- Accompany the inspector during the inspection.
- Take notes.
- Ask questions if you do not understand.
- Quickly correct cited violations.



Regulations 243

In North Carolina, most foodservice establishments are inspected four times per year. The frequency of inspection is dependent on the type of establishment.

The *NC Foodservice Rules Governing the Sanitation of Foodservice Establishments* (15A NCAC 18A . 2600) provide clear guidelines about how an inspection should be conducted. Inspections are conducted by an Environmental Health Specialist (EHS) authorized by the State of North Carolina to conduct a foodservice inspection.

Upon entry into the foodservice establishment, the EHS should identify themselves and their purpose in visiting the establishment. The EHS should ask to see the responsible person and invite that individual to accompany him or her during the inspection. If no employee is identified as the responsible person, the EHS can invite another employee to accompany them on the inspection. Following the inspection, the EHS should review the results of the inspection with the responsible person or the individual who accompanied them on the inspection.

The grading of the facility will be done on a standard inspection form available at: www.deh.enr.state.nc.us/ehs/Forms/DENR4007.pdf. Each operator should have a copy of the rules in their establishment and be familiar with the inspection form. You may download a copy of the rules at: www.deh.enr.state.nc.us/ehs/rules/t15a-18a.26.pdf

The inspection form includes, but is not limited to, the following information:

- the name and mailing address of the establishment;
- the name of the person to whom the permit is issued;
- the score given;
- standards of construction and operation as listed within the Rules book;
- a short explanation about all points deducted;
- the signature of the Environmental Health Specialist; and
- the date of the inspection.

In filling out the inspection form, points may be deducted only once for a single occurrence or condition existing within or outside of the foodservice establishment. Deductions must be based on actual violations that are observed during the inspection. The EHS can take zero, one-half, or a full deduction of points depending upon the severity of or the recurring nature of the observed violation. In determining whether items or areas of an establishment are clean, the EHS should consider among other things — the

age of the accumulated material, the relative percentage of items that are clean and not clean, the cleaning practices of the establishment, and the health risk posed by the circumstances.

Grading

The sanitation grade for all foodservice establishments is based on a system of scoring wherein all establishments receiving a score of at least 90 percent shall be awarded a Grade A; all establishments receiving a score of at least 80 percent and less than 90 percent shall be awarded a Grade B; all establishments receiving a score of at least 70 percent and less than 80 percent shall be awarded a Grade C. Permits will be revoked from establishments that receive a score of less than 70 percent. Beginning August 1, 2004, the numeric score will be posted along with the alphabetic grade.

An establishment can receive a credit of two points on its inspection score for each inspection *if* a manager or another employee responsible for the operation of the establishment who is employed full time in that particular establishment has successfully completed in the past three years a foodservice sanitation program approved by the Department of Environment and Natural Resources (DENR). Evidence that an individual has completed such a program must be maintained at the establishment and provided to the EHS upon request. An establishment must score at least 70 percent on an inspection to be eligible for this credit.

Upon initial inspection of a foodservice establishment or if a renovation or other change in the establishment makes the grade inconspicuous, the EHS shall designate the location for posting of the grade card. The grade card shall be located in a conspicuous place where the public upon entering the establishment will be able to easily see it. If the responsible person of the foodservice establishment objects to the location designated by the EHS, then the responsible person may suggest an alternative location that meets the criteria of the Rules.

Whenever an inspection of a restaurant, food stand, or drink stand is made, the EHS shall remove the existing grade card, issue a new grade card, and post the new grade card in the same location where the grade card was previously posted as long as the location remains conspicuous. The responsible person or operator of the foodservice establishment shall be responsible for keeping the grade card posted at the designated location at all times. The responsible person and the EHS may post the grade card in another location that meets the criteria of this Rule if agreed upon.

Re-inspection

Upon request of the permit holder or his or her representative a re-inspection shall be conducted. In the case of an establishment that has been closed for failure to comply with the *NC Rules Governing the Sanitation of Foodservice Establishments*, a re-inspection to consider the issuance or reissuance of a permit shall be made at the earliest convenience of the EHS. In the case of establishments that require an inspection for the purpose of raising the alphabetical grade/numerical score and that hold unrevoked permits, the EHS shall make an unannounced inspection after the lapse of a reasonable period of time that is not to exceed 15 days from the date of the request.

Risk-based inspections

North Carolina is moving toward conducting risk-based inspections and away from the traditional floors, walls, and ceiling approach to inspections, which focus more on sanitation than safety. The paradigm for conducting a risk-based inspection is different. An EHS would need to focus the inspection, set priorities, and assess active managerial control.

Focusing the inspection. To effectively conduct a risk-based inspection, the EHS has to focus on foodborne illness-related risk factors that are specific to the individual operation. These risk factors typically are associated with food handling practices and so directly impact food safety rather than with sanitation issues.

Furthermore, the EHS must model good practices. For example, they should: (1) wash their hands before beginning an inspection and after engaging in any activity that might contaminate hands; (2) sanitize

thermometer/thermocouple stems before and between taking food temperatures; (3) being careful not to touch ready-to-eat food with bare hands; (4) try not to contaminate cleaned and sanitized food-contact surfaces; (5) use an effective hair restraint; (6) have the proper equipment, such as a thermocouple and the appropriate sanitizer test kit(s); and (7) have a hot-holding thermometer or temperature-sensitive tape (thermolabels), flashlight, and individually packaged alcohol swabs.

Establishing priorities. The EHS also needs to establish priorities during the inspection. To begin with, he or she should review previous inspection reports to help detect trends. This is especially important in jurisdictions where inspectors frequently rotate. If the risk factors are out of control for more than one inspection, the EHS needs to work with the operator to develop intervention strategies to eliminate the problem. They also need to conduct a menu review. The menu review will help them to identify high-risk foods or high-risk processes. This review will also help them to assess the operational steps that often go unevaluated. After the menu review, the EHS needs to conduct a quick walk-through. This helps them observe activities that often go unnoticed. Finally, the EHS needs to establish an open dialogue to build a sense of partnership, to promote sharing of information, and to let the operator know what their food safety priorities are.

Assessing active managerial control. The EHS needs to assess critical limits that focus on documented foodborne illness risk factors. These include employee health, personal hygiene program, time-temperature management, cleaning and sanitization of food-contact surfaces, cross-contamination related to storage and preparation, and date marking. If out-of-control risk factors are identified, then the EHS must obtain on-site correction. The onsite corrections should be required for violations relating to risk factors and/or imminent health hazards. The purpose is to eliminate the immediate threat to public health and to convey the seriousness of the violation to the management.

For further questions about the inspection process, one can contact their local health department.