

Who Will Regulate My Food Business?

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Many governmental agencies are involved in regulating food. It is often confusing to try to understand the laws governing the processing, packaging and distribution of food products. Persons starting their own food business often call the local health authority to find information about getting started. As often as not, they are referred to another agency, then finally referred to the North Carolina Cooperative Extension Service.

The type of food and how it is prepared or processed will determine which agency has the regulatory jurisdiction. Federal, state, and county regulations require that foods be produced and maintained in a safe and wholesome manner. Each agency has a set of specific rules for products prepared or produced under its jurisdiction.

Foodservice

Ready-to-eat foods (foods served to the consumer for immediate consumption) and meals prepared on site are regulated by individual county health departments. County health departments use North Carolina foodservice rules as guidelines for regulating foodservice operations. These foods, whether served in a foodservice establishment, a food stand, or by a caterer are required to be prepared in a permitted establishment. Except in the case of catering, they must be served in or from a permitted establishment. The permit must be obtained in advance. Construction rules for facilities are strict. In North Carolina, plans must be submitted to the county health department prior to construction. A home kitchen is not allowed to be permitted except in the case of a bed & breakfast inn. Foodservice questions can be addressed to the environmental health section of your county health department.

Packaged Foods

Packaged foods, those which are wrapped and labeled for consumer purchase, are regulated by state agencies, usually under federal authority. In North Carolina, most packaged foods are regulated by the North Carolina Department of Agriculture (NCDA). Meat and poultry products to be sold only in NC are regulated by the NCDA Meat and Poultry Inspection branch. Meat and poultry products to be sold in interstate commerce are regulated by the Food Safety and Inspection Service (FSIS) of the USDA. Other processed foods are regulated by NCDA's Food & Drug Protection Division. Fluid milk products and shellfish products are regulated by the N.C. Department of the Environment, Health and Natural Resources' (DEHNR) Environmental Health Services Section.

Meat and Poultry

Meat and poultry products not to be shipped in interstate commerce must be processed in an establishment inspected and approved by the Meat and Poultry Inspection Branch of the NCDA. The USDA has jurisdiction for those products shipped to another state. Interstate commerce would include any operation which transports food across state borders. Slaughtering and processing facilities require buildings and equipment designed to predetermined standards and require prior approval. There are many other requirements of the operation, such as inspection of the individual animals' health, and labeling. In certain situations, on-site inspectors are required. Home processing facilities are not likely to be approved.

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**North Carolina
Cooperative Extension Service**

NORTH CAROLINA STATE UNIVERSITY
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Milk Products

Fluid milk products are regulated by rules adopted by individual states. The Grade A Pasteurized Milk Ordinance, has been adopted to by all states. It regulates the production, processing, and sale of products such as fluid milk, yogurt, and cottage cheese. These rules not only cover milk from the cow to the consumer, but also the cow and its health.

Milk for manufacturing purposes such as in the production of cheese, butter, and nonfat dry milk, is regulated as a processed food under the rules of the USDA. These rules are in turn enforced by the NCDA. Raw milk in both instances must come from inspected and approved dairy farms. Raw milk may not be sold to the consumer.

Shellfish and Seafoods

Shellfish (oysters, clams, mussels, scallops, etc.) harvesting and processing are regulated by the Shellfish Sanitation Branch (SSB) of DEHNR. The SSB also has jurisdiction for the crustacea, i.e., processing, packaging and distribution of cooked, ready-to-eat crab meat. Harvesting is actually regulated by DEHNR's Division of Marine Fisheries acting upon the recommendations of SSB. Shellfish shall be harvested from approved waters and require shipping documentation (tag) to that effect. Regulation of other seafood products is covered by rules adopted by the Food and Drug Administration (FDA) for the production of safe and wholesome foods. In addition, FDA will require written HACCP plans for the production and processing of seafood products by December 1997. NCDA Food and Drug Protection Division will carry out these rules in North Carolina.

Other Processed Products

Processed and packaged foods are regulated by the FDA. The Food and Drug Protection Division of the NCDA enforces these rules in North Carolina. Regulations governing these foods are found in Title 21 of the Code of Federal Regulations. These regulations consist of Section 100 and 101 concerning labeling and Section 110 which covers Good Manufacturing Practices along with other sections that contain Standards of Identity, acceptable ingredients, and other rules. In special cases where foods are preserved with added acid or low-acid foods are canned, (pH at 4.6 and above) Sections 114 and 113 apply, respectively. These sections have special requirements, such as establishment registration under Section 108, filing of a scheduled process, and processing and packaging under the operating control of a certified supervisor.

Products held under constant refrigeration, or that are determined to be naturally acid foods with a pH of ≤ 4.6 , or have a water activity (a_w) of ≤ 0.85 are not covered by the provisions of 21CFR 113 or 114. However, Good Manufacturing Practices (21CFR 110) requires that adequate controls be in place to assure the products continue to meet these parameters.

Summary

Food regulations can be confusing and often complicated. In many cases a single food product or production facility may be covered by multiple jurisdictions. Almost all processing of foods requires prior notification to the regulatory agency.

Across all jurisdictions, food must be produced, processed, and held in a manner which prevents spoilage and contamination to keep it wholesome. Processing establishments must submit to unannounced inspections of the building and grounds. Unhealthy or ill persons must not be allowed to handle foods and pets are not allowed. For these reasons and others, home kitchens are not usually considered appropriate for processing purposes.

Because of the many rules for processing and preparing food for sale, the entrepreneur is advised to consult an expert prior to investing in a food processing venture. As in any business venture, know and understand the rules before you get started.

Some Useful Addresses

N.C. Department of Agriculture
Meat and Poultry Inspection
P.O. Box 27647
Raleigh, NC 27611-7647
919/733-4136

Food and Drug Protection Division
4000 Reedy Creek Road
Raleigh, NC 27608
919/733-7366

N.C. Dept. of Environmental Health and Natural Resources
Division of Health Services
Environmental Health Service Section
P.O. Box 27687
Raleigh, NC 27611
919/733-2884

Shellfish Sanitation Branch
P.O. Box 769
Morehead City NC 28557
919-726-6827

North Carolina State University
Department of Food Science
Box 7624
Raleigh, NC 27695-7624
919/515-2956

United States Department of Agriculture
Food Safety and Inspection Service
4407 Bland Road, Suite 270
Raleigh NC 27609
919-790-2828