

Who Will Regulate my Food Business?

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Many Governmental Agencies Regulate Foods

- County, state and federal agencies are parts of the picture.
- It is often confusing to try to understand the laws governing the processing, packaging and distribution of food products.
- Each agency has a set of specific rules for products prepared or produced under its jurisdiction.

General Observations

- The type of food and how it is prepared or processed determines 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.
- Required to be prepared in a permitted establishment.
- Except in the case of catering, they must be served in or from a permitted establishment.

Home Foodservice

- A home kitchen is not allowed to be permitted except in the case of a bed & breakfast inn.
- 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.
- Foodservice questions can be addressed to the environmental health section of your county health department.

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Packaged Foods

- Packaged foods are those which are wrapped and labeled for consumer purchase.
- They are regulated by state agencies, usually under federal authority.
- In North Carolina, most packaged foods are regulated by the North Carolina Department of Agriculture and Consumer Services (NCDA&CS).

Meat and Poultry

- Meat and poultry products to be sold in interstate commerce are regulated by the Food Safety and Inspection Service (FSIS) of the USDA
- Products to be sold only in NC are regulated by the NCD&CS Meat and Poultry Inspection Branch.

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&CS.
- The USDA has jurisdiction for those products shipped to another state.
- Interstate commerce would include any operation which transports food across state borders.

Special Requirements

- 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.

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

- Milk products such as cheese, butter, and nonfat dry milk, are regulated as processed foods under the rules of the USDA.
- These rules are in turn enforced by the NCDA&CS.

Raw milk

- Milk used for fluid for manufacturing purposes 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 Section of DENR.
- They also have jurisdiction for the crustacea, i.e., processing, packaging and distribution of cooked, ready-to-eat crab meat.
- Harvesting is actually regulated by DENR's Division of Marine Fisheries.

Shellfish

- DENR's Division of Marine Fisheries acts upon the recommendations of the Shellfish Sanitation Section of DENR.
- Shellfish shall be harvested from approved waters and require shipping documentation (tag) to that effect.

Regulation of Other Seafood Products

- Covered by rules adopted by the Food and Drug Administration (FDA) for the production of safe and wholesome foods. In addition, FDA will requires written HACCP plans for the production and processing of seafood products.
- NCDA&CS 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.

Low Acid and Acidified Foods

- 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.

Refrigerated and Foods With High Acid or Low Water Activity

- 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.

General Requirements

- 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.

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.
- All plants must register with the FDA or FSIS.

Remember

- 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.