

Limited Food Manufacturing

Limited food manufacturing is the production of a single food product, or a limited food product line. Examples of these types of foods are candies, baked items, sauces, salsas or dry mixes. Limited food manufacturers are required to get an operating permit from the Health Department. Food item(s) must be prepared in an approved, permitted food establishment.

Plan Review

Limited food manufacturers who plan to construct a food establishment where food will be produced are required to follow the standard plan review procedures before an operating permit is issued. The fee for plan review is \$480.00 for a fixed food establishment and \$230.00 for a mobile food establishment. Before the business can manufacture food, an onsite inspection is required. The fee for this inspection is \$56.00.

Modified Plan Review

You may choose to use an already permitted food establishment in Pima County in which to make and package your food. The food establishment must have a valid operating permit issued by the Pima County Health Department. To use this food establishment, you are required to submit a modified plan review with the appropriate plan review fee for *Other Health Review*, which is \$66.00. In addition, there is a \$56.00 inspection fee to conduct the final, pre-operational inspection before the business can begin to manufacture food products. The modified plan review must be typewritten and include the following information:

1. A **marketing plan** disclosing how the product will be marketed or distributed, such as:
 - Direct to the consumer at the manufacturing site or delivered to the consumer locally
 - To businesses for use in their operations as an ingredient or as part of their menu
 - To businesses for direct sell to the consumer from a display
 - Direct to the consumer via the Internet
 - At farmer's markets where sampling will be conducted before the sale
2. A **notarized, written agreement** between the food manufacturer and the food establishment's permit holder.
 - In the agreement the permit holder must authorize the manufacturer to use the food establishment, and state that all food ingredients, finished food products, and food equipment are stored at the food establishment.
 - No ingredients, equipment or finished food products may be stored in any other location without the location being approved by the Pima County Health Department. This includes warehouses, storage companies, residences, etc. Multiple locations will require approval from and additional permits issued by the Pima County Health Department.
3. A **complete list of food products** being made.
4. A **list of all ingredients** (fresh, frozen or canned) and the **processing methods used for each product**. A validated HACCP plan and product testing may be required depending on the type of food product produced and processing methods. Validated HACCP plans and product testing are

the responsibility of the food manufacturer.

5. A **list of the food equipment** used. All equipment used must meet standards in the Arizona Food Code 4-205.1: American National Standards Institute (A.N.S.I.) or equivalent standards. The make, model and specifications for any uncommon or specialty food equipment is required.
6. How finished product will be transported and delivered, include any specialty equipment required for temperature control.
7. The **types of packaging** for the product and the **names of the suppliers** of the packaging materials. Selected packaging must have provisions to prevent tampering such as heat sealed plastic bands or tamper evident caps.
8. A **sample of the labeling** that meets the requirements of the Arizona Food Code, Chapter 3-602.11.
9. Any **additional labeling requirements** as stipulated by FDA or USDA regulations.
10. The **training or other education** the Person in Charge will receive before the food operation begins. The Person in Charge must be able to comply with the Arizona Food Code, Chapter 2-102.11 by the date of the onsite inspection.
11. Food products may require approval of other agencies, such as the Food and Drug Administration (FDA) and/or the United States Department of Agriculture (USDA).

Quality Assurance

To insure the safety and shelf stability of the food products, the Health Department may require testing. Arrangements for testing and reporting of the test results to the Health Department are the responsibility of the food manufacturer.

Plan Review

The plans submitted must be complete before they will be evaluated. Only complete plans including all required information as outlined will be evaluated. The notarized agreement does not guarantee approval of selected location for manufacture.

Final Approval

After the plan is reviewed and approved an onsite inspection of the food establishment is conducted. The manufacturer must submit an application for the operating permit, and pay the permit and inspection fees before this onsite inspection.

Only after the Pima County Health Department issues written approval of the food establishment can food preparation begin.