



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 specialty foods, baked items, sauces, salsas or dry mixes. Limited food manufacturers are required to have 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.

You may choose to use a permitted food establishment in Pima County to prepare your food products. 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 limited food manufacturing plan review. The fee for plan review 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 plan review must 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 may be conducted before the sale
2. A **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** to be prepared, a **list of all ingredients** (fresh, frozen or canned) and the **processing methods used for each product**.
4. A **list of the food equipment** used. All equipment used must meet standards in the Pima County Food Code 4-205.10: 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.

5. How finished product will be stored, transported and delivered, include any specialty equipment required for temperature control.
6. 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.
7. A **sample of the labeling** that meets the requirements of the Pima County Food Code section 3-602.11. including any **additional labeling requirements** as stipulated by FDA or USDA regulations.
8. Required **food safety training**, the Person in Charge must be able to comply with Pima County Food Code sections 2-102.11 **Demonstration** and 2-102.12 **Certified food Protection Manager** by the date of the final pre operational inspection.
9. 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 and Product Safety

To ensure the safety of the food products produced, the Health Department may require product testing. Arrangements for testing and reporting of the test results to the Health Department are the responsibility of the food manufacturer.

A variance and validated HACCP plan (prepared by a processing authority) with product testing are required for food products produced using specialized processing methods such as fermentation, reduced oxygen packaging and using food additives as a method of food preservation (Sushi Rice, Salsa). Validated HACCP plans and product testing 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 kitchen use agreement does not guarantee approval of selected location for manufacture. Plans must be submitted using the online portal at <https://webcms.pima.gov/cms/One.aspx?portalId=169&pageId=431>

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.