Food Entrepreneurs Series: Rules and Regulations

What is a Scheduled Process?

A scheduled process is an important component of your food production, especially if you are producing acidified food items. Each acidified food item that you make must have a scheduled process that has been compiled with the assistance of a process authority, and the scheduled process shall be followed each and every time you have a production run. It is ***illegal*** to sell a shelf-stable, canned acidified food product without obtaining a scheduled process and filing with the FDA first.

What exactly *is* a scheduled process?

A scheduled process is a detailed procedure developed for a specific product which includes information about product ingredients and formulation, processing specifics (times, temperatures, process flow), critical control points (pH, water activity, etc.), primary packaging, storage, and/or distribution. All specifics of the scheduled process must be met each time a batch of product is made, and the processor is responsible for documenting their actions to prove they adhered to their scheduled process. A scheduled process must be developed by a process authority that has expert knowledge in the processing of the particular food item in question.

According to the FDA, a scheduled process means: the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority.

What is the purpose of a scheduled process?

Scheduled processes are necessary in order to establish a method of food production that has been scientifically verified to produce safe food. If you are canning an acidified food product, there is potential that you could create an environment that is favorable for the growth of the pathogenic microorganism *Clostridium botulinum*. *Clostridium botulinum* is the bacterium that causes the disease botulism. Botulism can be deadly, but it is preventable through proper acidification and heat processing of food. In order to be sure that all canned foods that have the potential to support the growth of *Clostridium botulinum* are produced safely, a scheduled process is necessary and must be followed each and every time the food is produced.

What is a process authority and where can I find one?

A food processing authority for acidified foods is a person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods. This person understands the details of food safety as it applies to an acidified food product, and can give you specific requirements for processing your food in a safe manner. Many land-grant universities offer services to food processors in the states they serve to do food testing and provide scheduled process letters. A fee is generally charged for these services. There are also a number of private labs across the country that are qualified acidified food process authorities.

What do I do once a scheduled process has been developed for my product?

Once you have a scheduled process for your food products, there are a number of things you need to do in order to begin selling your item. First of all, if you are making an acidified canned food, you will need to register your facility with the FDA (form 2541) in addition to filing your scheduled process for each food you are planning on selling using FDA form 2541a. Acidified food processors are required by the FDA to take a Better Process Control School course. You will also need to contact the Virginia Department of Agriculture and Consumer Services to get your process inspected.

What do I have to do now that I have filed my scheduled process?

A scheduled process is not a free ride to make food for sale with no reservation. There are things you must keep in mind when making your food. Your scheduled process dictates the important critical control points that must be met each and every time you make a batch of food. If you do not meet the critical control points as listed in your scheduled process, then your food is considered adulterated and not legal for sale. In order to prove that you have met the critical control points necessary for your food products to be safe, you have to keep records. Keeping records of your critical controls points each time you process food is a requirement. Any time you deviated from your scheduled process, you must note the deviation that occurred and what you did to correct that action. You must maintain these records in a separate file and you must keep these records for three years before you may discard them.

For more complete information regarding requirements of acidified food processing, please consult the Code of Federal Regulations 21 CFR 114: Acidified Foods, available at this link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=114&showFR=1