

Defining a Process Authority

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I am often asked what a process authority is and what their responsibilities are. The answers to these questions give us a better understanding of the process authority's essential role in the food processing industry.

The Regulations: A Changed Industry

In the "old days" (before 1971) it was easy to get a process for thermally processed foods. The processor simply contacted a container supplier, equipment manufacturer or the National Canners Association (subsequently called National Food Processors Association now known as the NPA) to secure this information.

That all changed in the summer of 1971 as a result of two incidents of contamination of commercially canned soups with *Clostridium botulinum*. In January 1973 the Food and Drug Administration (FDA) issued Title 21 Code of Federal Regulations Part 128B entitled "Thermally-Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" (since recodified as Part 113). Additionally, a second regulation was promulgated and designated as 21 CFR Part 90 (since recodified as Part 108b). Part 128b went into effect in March 1973 and Part 90 (the Emergency Permit Control) in April 1974. These two regulations changed the regulatory scrutiny of the commercial canning industry forever.

Today, it isn't as easy to establish a process as it was prior to the regulations. Advances in food processing technology have created an array of process control choices for the manufacturer. The regulations cover the important foundation aspects of canning operations including process establishment, process delivery equipment, process deviation handling, record keeping, and container integrity. The FDA and U.S. Department of Agriculture (USDA) have, throughout their regulations, made references to "competent processing authorities". Part 113.83 of 21 CFR refers to "establishing scheduled processes" and states:

"Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors, e.g. minimum headspace, consistency, maximum fill-in or drained weight, water activity (aw) , etc. that may affect the scheduled process, shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, microbial thermal death time data, and inoculated packs. Calculation shall be performed according to

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procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation, they shall include containers from test trials and from actual commercial production runs during the periods of instituting the process. The incubation tests for confirmation of the scheduled processes should include the containers from the test trials and a number of containers from each of the four or more actual commercial production runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination."

This section of the regulation mandates that scheduled processes for low-acid foods be established by *qualified* persons: having expert knowledge in the heat sterilization of low-acid canned foods. Having facilities, instrumentation, and equipment adequate to determine the heat processing requirements of the food product. Adequately providing for the type, range, and combination of variations encountered in commercial production when the scheduled process is established. Using acceptable scientific methods of establishing heat sterilization processes including the use of appropriate F and z values and/or the development of bacterial spore thermal-death-time data. Maintaining records which cover all aspects of the process.

While this general description covers how a process will be established, it does not speak directly to of who process authorities are or how one qualifies to be a process authority. In Part 113.89 "Deviation in processing, venting, or control of critical factors" the regulation states:

". . .such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to the public health."

The Process Authority: Definitions and Responsibilities

Unfortunately, when you look up Part 113.3, "Definitions", you will quickly realize that there is no definition listed for what constitutes a process authority. So what is a process authority and what are its responsibilities? The closest existence to a definition of a process authority by the FDA is contained within the "legalese" of the regulations.

The regulations have established the process authority as a "go between" for the FDA and the processor, with respect to compliance with the regulations and evaluation of any potential hazard to public health risk. As a "go between" for the regulatory agencies and the food processor, the process authority works to reach solutions that are reasonable to both the processor and the regulatory agencies and comply with the intent of those regulations.

According to the USDA regulation 9CFR 318.300, entitled "Definitions", a processing authority is

"the person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart."

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Using regulatory definitions and descriptions as a foundation, perhaps looking at the many responsibilities a process authority holds under these regulations will paint a clearer, more realistic picture of a *process authority*. Process authorities have many responsibilities under the regulations. They must establish processes, evaluate processing deviations and keep adequate records of the work done in these areas. Many times they must assume other responsibilities not so clearly delineated in the regulations.

The process authority must recognize the inadequacies or inexperience of a processor in order to provide him with sufficient information to ensure that the processor understands what factors are operationally critical, how to monitor and control them, and what he must do when process failure occurs. The process authority must thoroughly investigate and completely understand innovations or new developments in equipment, product formulation, methods of processing, or any other area and must identify all critical factors which may adversely affect the product/package safety.

Over the years, FDA officials have stated in various presentations that process authorities are required to have knowledge in a variety of scientific disciplines including microbiology, engineering, mathematics, food technology, chemistry, metallurgy and physics.

Who is Qualified? The View from FDA and USDA

Various FDA personnel have tried to further define the question of process authority. Although the FDA does not maintain a list of individuals or groups who qualify as process authorities, FDA has acknowledged that there are certain individuals or groups whose training and experience qualify them to develop processes and evaluate the public health significance of any process deviation. There are certain organizations whose knowledge and methods are generally recognized by their peers as constituting competency. Basically, this should be a body of collective individuals who routinely make thermal process determinations in a production plant environment, not someone who does this as a sideline activity or as one of many other professional duties.

Process Authorities Must Have Ongoing Experience

To qualify as a process authority, the individual or group must have the expert knowledge that comes from developing processes and evaluating process deviations on a **regular basis**.

A Person or an Organization

With respect to low-acid canned foods, it is extremely difficult — if not impossible — for any **individual**, acting alone, without any input/review from others, to be singularly knowledgeable about all the factors related to heat resistance, temperature distribution, and how any given product would heat in any given container. ... It is worth noting that 114.83 states that scheduled processes for acidified foods shall be established by "a qualified person", while 113.83 states they shall be established by "qualified **persons**". The rather lengthy description of required procedures and data in 113.83, as well as the emphasis on having adequate facilities, virtually ensures the difficulty of a single individual, acting alone, in being considered a process authority.

Thus, while an individual may sign a letter to the firm which delineates the factors critical to temperature distribution or process establishment, this is done on the letterhead of an **organization**,

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which, in turn, purports to stand behind the statements made by the individual. "The source of the thermal process is the very foundation of everything you do in a low-acid canned food or acidified food operation. ... Short changing your process authority on the information he or she needs to establish the process can result in one which is inadequate."

In the FDA's Inspection Operation Manual, Inspectional Methods, a section addresses what information is to be requested about a firm's processing authority, by the FDA investigators where FDA is not familiar with the particular process authority named by the processor. In such a case, the investigator is instructed to request the following information:

- Individual's name
- Individual's work affiliation
- The individual's academic and industrial experience related to thermal processing work
- General procedures used to evaluate deviations, such as an overall experimental plan for development of data, penetration and distribution test data and microbiological data when appropriate.
- Details of actual experimental methods used, including heat penetration and distribution test data, and microbiological data when appropriate
- Protocol for making conclusions based on experimental data.
- The F_0 value (a measure of lethality) judged necessary to destroy spores of *Clostridium botulinum* in each product under consideration and the method of calculation of the F_0 value
- The equipment used to perform the experiments, including manufacturer, model number, state of repair, and other pertinent data
- The accuracy of the test instruments and other equipment, and the record showing that the instruments were routinely calibrated with an accurate standard
- Any other facts which have a bearing on the adequacy of the evaluations

The FDA's views on process authorities have been defined for the industry:

". . . 113.83 states they (scheduled processes) shall be established by 'qualified persons'. The rather lengthy description of required procedures and data in 113.83, as well as the emphasis on having adequate facilities, virtually ensures the difficulty of a single individual, acting alone, in being considered a process authority." ". . .with respect to low-acid canned foods it is extremely difficult -- if not impossible -- for any individual, acting alone, without any input/review from others, to be singularly knowledgeable about all the factors related to heat resistance, temperature distribution, and how any given product would heat in any given container." ¹

¹ William R. Cole, Investigator, USFDA Office of Regulatory Affairs, Division of Field Investigations, International Programs and Technical Support Branch, in his opening remarks to the Better Process Control School.

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In 1983, the FDA further defined the role of a process authority:

"Basically a processing authority is a person who has expert knowledge of thermal processing requirements for low-acid foods packaged in hermetically-sealed containers or has expert knowledge in the acidification and processing of acidified foods." "The term 'expert' implies experience, knowledge, and achievement, as well as recognition as an authority on a subject, usually by ones peers." "Being a processing authority requires knowledge in a variety of disciplines such as microbiology, engineering, mathematics, food technology, chemistry, metallurgy, and physics. More importantly, practical experience under actual operating conditions is essential. What happens in the text books or laboratory does not always happen in the plant and vice versa."

"The FDA has no specific statutory authority to require that processors obtain our prior approval before engaging the services of an individual or an organization to act as a processing authority. We do not intend to institute such approval procedures nor to generate a list of competent processing authorities. The regulations are intended to govern the end product of a processing authority's work rather than that person's qualifications to conduct the work. However, we may need to review a person's qualifications and the procedures and methods used to evaluate the adequacy of the final work product."

"There are certain groups and individuals whom we generally recognize as processing authorities. We recognize them as processing authorities primarily because they are routinely engaged in such activities and because of our knowledge of the qualifications of their personnel for establishing processes and for conducting evaluations in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential public health hazard. The acceptability of a person as a processing authority is determined by the acceptability of the procedures used and the proficiency of the execution of those procedures. Even though we recognize certain groups or individuals as being processing authorities, this does not imply that we will never question their work. Some of you have been questioned by us in the past. We do not blindly accept the word of these individuals or organizations all the time, but review each situation on its own merits. We may scrutinize a particular situation less if we have had experience with the individuals as to their methods and procedures and are familiar with the product involved. I do not want to imply that we play favoritism. If identical situations occurred where we questioned a process or deviation evaluation, we would request an explanation or data substantiating the conclusions regardless of whether we had knowledge of the person's qualifications."

"Processing authorities have many responsibilities under the regulations. They must establish processes, evaluate processing deviations, and keep records of the work done in these areas."

"Another responsibility of a processing authority is to keep records of the work done. 21 CFR 113.83 states: 'Complete records covering all aspects of the establishment of a process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.' 21 CFR 113.89 states: 'A record shall be made of the evaluation procedures used and the results.' "

"The sections of the regulations dealing with venting require that heat distribution data, or documentary proof demonstrating that adequate venting is achieved, be kept on file. The reason for keeping these records is that Section 108.35 (c) (3) (ii) states that when requested by FDA in writing, a processor shall provide FDA with 'any information, concerning processes and procedures, which is deemed necessary . . . to determine the adequacy of the process.' "

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"If an investigator is not familiar with the person conducting this work, he may request information about the person's work affiliation, academic and industrial experience (as related to thermal processing), procedures and methods used, details of the actual tests conducted, protocol for making conclusions, minimum health and commercial sterility sterilizing values, heating factors used or obtained, accuracy of test equipment, etc."

"It is essential that persons who are involved in process establishment, deviation evaluation, and other aspects of the thermal processing of low-acid canned foods maintain current knowledge of new developments in the canning industry."

"A processing authority must always keep in mind that his ultimate responsibility is to protect the public health. To do this you must maintain your expertise. You must also be familiar with federal regulations and policies in order to provide the processor with appropriate information." ²

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USDA 9CFR 318.302(b) "Source of Process Schedules" states:

Process schedules used by the establishment shall be developed by a process authority. Any change in product formulations, ingredients or the treatments that may affect either the product heat penetration profile or the sterilizing value requirements shall be reviewed by the firm's process authority. Complete records concerning all aspects of the development or determination of a process shall be made available to USDA.

In a very clear definition, both the USDA and FDA insist upon the use of knowledgeable persons or organizations in process establishment activities, including products in novel containers.

Process Authority's Responsibilities

A true process authority has a unique perspective. The authority has access to gather information from scientific clearing houses and plant facilities. The authority also usually knows the legal codes upon which their position is mandated.

The process authority:

- Has responsibility in all product safety areas of product/container handling in the plant.
- Is a critical decision-maker in plant disputes.
- If an in-house authority, stays in contact on a regular basis with outside authorities.
- Has regulatory credibility.
- Is non-aligned to other internal parties and specialized internal corporate interests.

² "The View from FDA" included in "Capitalizing on Aseptic". William R. Cole, Fred A. Phillips, USFDA Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Enforcement, presented at NFPA's October 1983.

³ "Regulatory Aspects of Process Authorities in Low-Acid Canned Food Matters" William R. Cole, Fred A. Phillips, presented at Second Annual Conference on the Responsibilities of Process Authorities sponsored by the Institute of Thermal Processing Specialists (IFTPS). November 1982.

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A process authority is responsible for the development of unique test protocol for thermally processed foods, integrating requirements of the container, process equipment, and product. The authority needs to first make the decision on product/packaging failure thresholds. Second, these thresholds need to be evaluated and defined as critical factors to the process where necessary. Third, these critical factors must then be properly translated into commercial applications. In addition, the authority maintains regular regulatory communication, particularly when new technology is considered.

One of the most important requirements of the process authority is to properly utilize the most technically appropriate and advanced data collection and evaluation techniques, which can be used to generate the most accurate results possible. These methods will include, where applicable, the use of computers, specialized thermal process evaluation software, such as CALSoft II and NumeriCAL, specialized data collection devices, and special mount thermocouples for data collection purposes.

The process authority must properly evaluate all "total system" test data. These data are in the form of equipment qualifications, retort computer control programs, heat penetration tests, temperature distribution tests, lethality distribution tests, microbiological heat resistance and microloading studies, critical product and process delivery related factors.

This information must be translated into useable process development strategies for key participants in a particular project. The authority has to have a depth of experience. A good process authority will keep all customer process establishment and evaluation technical files open for regulatory review and will justify process instructions provided to the user by extensive documentation.

Although there is not any one definition that encompasses all that a process authority is and does, the FDA and USDA personnel for the enforcement of FDA and USDA LACF regulations have definite views in the area of process authority status. But considering that selection of a process authority is one of the most critical decisions a food processor will make, it is imperative that the processor has a thorough understanding of what a process authority is and what role it plays in the production of a product.

The process authority must:

- Be willing to share with the canner/processor all of the explicit and implied responsibilities imposed by the regulations
- Be able to evaluate a processor's total processing operations from raw materials to finished product storage and distribution.
- Advise the processor of both the regulatory impact and, more importantly, the health risk that any change in operations might cause.

The whole processing world has expanded over the years. In the old days, processors were challenged with steam and water process vessels, hydrostats and Sterilmatics. Containers consisted of various size cans and glass jars. Today we are faced with these items as well as with more advanced in-container process systems, such as static and rotational, steam air, shower, and full immersion water processes. In addition, particulate aseptic, microwave, irradiation, and high pressure sterilization systems are emerging.

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Future Challenges

The aseptic area is one worth mentioning; however, is a complete topic in itself. But these aren't the only new challenges the thermal processing industry faces. Food packaging and containers have also changed in recent years and have a tremendous impact on the way foods are processed. Flexible pouches, plastic containers, and other packaging forms have entered the thermal processing arena.

When one steps back and looks at all of the responsibility the processor and process authority must share, it should appear terrifying. The process authority needs almost to be a fortune teller; able to see the entire potential problem areas associated with processing, in advance of establishing a process. The responsibility is quite comprehensive and should not be entrusted to the inexperienced players.