

## What is a Process Authority?

TechniCAL often refers to itself as one of the industry's leading process authorities. But what exactly is a process authority? What are process authority responsibilities and who decides who or what is and isn't a process authority? What is the process authority's 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 Cannery Association (now known as the National Food Processors Association) 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,  $a_w$ , 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 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, if one refers to Part 113.3, "Definitions", he or she 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 9 CFR 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."

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 & 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.

*The point to be made is this:* 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**.

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**, 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:

- A. Individual's name
- B. Individual's work affiliation
- C. The individual's academic and industrial experience related to thermal processing work
- D. 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
- E. Details of actual experimental methods used, including heat penetration and distribution test data, and microbiological data when appropriate
- F. Protocol for making conclusions based on experimental data

- G. 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
- H. The equipment used to perform the experiments, including manufacturer, model number, state of repair, and other pertinent data
- I. The accuracy of the test instruments and other equipment, and the record showing that the instruments were routinely calibrated with an accurate standard
- J. Any other facts which have a bearing on the adequacy of the evaluations

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, appropriately stated FDA's views related to process authorities. The following are excerpts from his presentation:

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*". . .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."*

Fred A. Phillips, USFDA Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Enforcement, added the following remarks, excerpted from his presentation at NFPA's "Capitalizing on Aseptic", October 1983, entitled "The View from FDA", and also "Regulatory Aspects of Process Authorities in Low-Acid Canned Food Matters" presented November 1982 at the Second Annual Conference on the Responsibilities of Process Authorities sponsored by the Institute of Thermal Processing Specialists (IFTPS):

*"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."*

*"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."*

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

- A. Process schedules used by the establishment shall be developed by a process authority
- B. 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
- C. Complete records concerning all aspects of the development or determination of a process shall be made available to USDA.

In 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 Authorities: Their Abilities:**

More companies are developing their own in-house process authority structure. However, companies have been found to rely on the advice of an exclusive employee within their own organization as a "process authority". Beware of the individual who uses the pronoun "I" as in "I am a process authority." Many outside consultants and even vendors and sales people are using the term loosely and dangerously. A true process authority has a unique perspective. The authority has access to information from scientific clearing houses and plant facilities. The authority also usually knows the legal codes upon which their position is mandated. The 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.

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 (CALSoft and NumeriCAL), specialized data collection devices (CALPlex), and special mount thermocouples for data collection purposes (Ecklund Thermocouples).

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.

## **Choosing a Process Authority: an Important Decision**

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. 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 all of the 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.

Suppose you or one of your family members need heart surgery. Would you get advice and arrange surgery with:

- A. a friend who went to medical school but didn't finish?
- B. the nurse at your company facility?
- C. a biomedical engineer who designs heart valves?
- D. the local medical supply house because they sell heart valves and know the medical terms?
- E. a general practitioner who specializes in nothing and does a lot of research?

- F. a community hospital that has a reputation for performing numerous surgeries, but the medical staff keeps changing?
- G. the most qualified heart surgeon who has both knowledge and experience, performs surgery on a regular basis, and has the most successful post-operative results?

**We think your decision would be obvious.**

The selection of your process authority is a similar decision. The recommendations, advice, and establishment of the thermal process by your process authority is at the very "heart" of your processing operation. As in the metaphorical illustration above, failure to ensure that the processor is getting competent advice based on knowledge and experience means placing the processing "operation" at regulatory "risk". More importantly, the public "health" is now "endangered". 