PROCESSING AUTHORITIES

[21CFR113.83 and 113.89]

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. Knowledge can be obtained by education or experience or both. Expert implies experience, knowledge and achievement as well as recognition as an authority on a subject, usually by one's peers. Anyone who is establishing scheduled processes must have adequate facilities for making the appropriate determinations (21 CFR 113.83). Anyone who is evaluating processes which are less than the scheduled process must utilize procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health (21 CFR 113.89).

Some have asked FDA if a certain individual can be approved as a processing authority. 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. FDA does 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. However, if CFSAN (HFS-617-Division of HACCP, Regulatory Food Processing and Technology Branch) is unfamiliar with the person/establishment they may need to review their qualifications, and the procedures and methods utilized to evaluate the adequacy of the final work product.

There are certain groups and individuals, such as trade associations, equipment manufacturers, food consulting firms, food container manufacturers, academic institutions, professors, and firms with a thermal process expert on their staff. FDA often has 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; and they are routinely engaged in such activities. Even though they may be recognized by their peers as being processing authorities, this does not prevent the agency from performing inquiries.

What are the responsibilities of the processing authority? First a processing authority must establish thermal processes (21 CFR 113.83).

Without a properly established process, process control at the processor is useless. Establishing processes requires among other things; 1) considerable knowledge about product characteristics and the effect of each processor's equipment and procedures on those characteristics of importance to heat penetration; 2) experience in conducting heat penetration, temperature distribution, thermal death time studies and other scientific methods; and 3) the ability to determine through evaluation of data generated by these studies and tests, that sufficient testing has been accomplished to identify all possible factors that could affect the heating characteristics of the product and the safety of the final product.

The written documentation delineating the scheduled process should include initial temperature, process time, process temperature and least sterilizing value, and also address such items as formulation, if critical, and maximum or minimum values of other critical factors.

A processing authority is also responsible for establishing the adequacy of temperature distribution in retorts, including the establishment of venting schedules for retorts using pure steam (unless venting schedules referenced in 21CFR Part 113.40(a)(12)(i)or(ii) are used, provided that the retorts are equipped according to specifications in Part 113), or retort come-up procedures for retorts using water immersion, water sprays, or steam air mixtures.

21 CFR 113.40(a)(12)(iii) also permits other installations and procedures, provided there is evidence, in the form of heat distribution data kept on file, demonstrating that the equipment and procedures accomplish adequate venting of air.

Occasionally process authorities develop venting procedures that do not specify minimum vent time. Such a vent procedure would be specific for a particular installation; would be based on reaching a minimum retort temperature; and would be developed by performing heat distribution studies involving the shortest possible time to achieve a minimum temperature.

Automating the vent procedure and/or avoiding the need to record the 'time vent closed', are just two reasons why a processing authority might consider developing a vent procedure of the type described. For example, a process authority may determine for a specific installation that the shortest possible time to reach 225^0 F is 4 minutes. If the studies show adequate heat distribution is achieved when 225^0 F is attained, time vent closed would not be a necessary component of the recommended venting procedure and would not need to be recorded. In cases where the venting, and/or retort installation and procedures are not as specified in 21 CFR 113, contact CFSAN (HFS-617) to determine if an evaluation is necessary.

It is often necessary for a processing authority to recognize the inadequacies or inexperience of a processor in order to provide the processor with sufficient information to ensure understanding of what factors are critical; how to measure them; and how to control them. For example, maximum fill drained weight (of solids after brining) may be listed as a critical control factor. A processor may control fill weight by conducting tests before brine is placed into the can, without realizing that these tests are not measuring the identified critical factor. Another example is sauce viscosity which often has to be measured within the correct temperature range using a specific instrument as studied during heat penetration testing. Failure to properly convey critical factor methodology could result in the failure to deliver the scheduled process. In some cases, it may suffice to state that a particular factor is not critical (i.e., headspace, if cans without headspace were used in the tests).

A processing authority is responsible for the evaluation of processing deviations (21 CFR 113.89); to determine whether a specific lot is, or is not, a potential danger to health. The decision is usually based only on the review of processing and production records, which are presumed to be accurate. The processing authority may assume that other factors were controlled, and that equipment, including measuring devices, were properly adjusted (some processing authorities make a statement in their evaluation letters to the effect: provided all other processing parameters were in conformance...). In most cases, these assumptions are valid, but records should be carefully reviewed for any indications of discrepancies. The processor should submit the fill weight records, or records documenting control of other critical factors when there has only been a temperature drop. If the processing authority cannot verify that all other critical factors were controlled, a complete and accurate evaluation cannot be made.

If the deviations submitted to the processing authority were discovered by an FDA Investigator, the Investigator should stress to the firm that the FDA 483 should be submitted to the processing authority with the other records covering the process deviations. For example, the Investigator may have observed higher fill weights than the records indicate or that the firm determines fill weight improperly; critical information when evaluating a deviant process.

he processing authority's evaluation report should contain sufficient information to document that the deviant process is commercially sterile, meets the requirements for the minimal thermal process, or is unsafe. In all cases the report should list the critical factors considered in the evaluation.

Although there are situations in which FDA may need to know the actual maximum or minimum values for the critical factors considered, and the heating factors to determine if a proper evaluation has been made, there are legitimate reasons for not including this information in an evaluation report to the processor. An example, is a case where a deviation evaluation report listed the fill weight used in the evaluation of a deviant process that happened to be greater than the maximum fill weight listed in the scheduled process. When a FDA investigator found fill weight in excess of the scheduled process at this firm, the firm's manager told the investigator that this fill weight was an authorized process, based on the previously referenced process deviation evaluation report. The initial report should have reminded the firm that their filed process fill weight value was the scheduled fill weight, and deviations from this weight should be used to identify a process deviation.

If the processing authority evaluates a deviant process as unsafe they should inform the firm of their options (reprocess in accordance with a process established by qualified individuals, or destroy) and remind them the FDA must be notified if any product has been distributed.

The processing authority must keep complete records covering all aspects of the establishment of a scheduled process, including associated incubation tests (21CFR 113.83), and all records covering deviation evaluation procedures used and the results (21CFR 113.89). The sections of the regulations dealing with venting or retort come-up (21CFR 113.40) require data or documentary proof demonstrating adequate temperature distribution, be kept on file.

When requested by FDA in writing, a processor must provide FDA with any information concerning processes and procedures which is deemed necessary... to determine the adequacy of the process (108.35(c)(3)(ii)). In many instances, the information requested, such as heating factors, heat penetration data, conditions of the heat penetration tests, minimum public health sterilizing value, etc., will be in the possession of the processing authority. FDA realizes that processing authorities do not generally like to provide this information to the processor. When processing authorities are not employees of the processor, FDA does not request this information directly. If a processing authority does not wish to provide the requested data and information to the processor, the FDA investigator should obtain a written release from the processor to permit FDA to acquire the data and information directly from their processing authority. FDA is required by law to protect the confidentiality of this information.

An example of an inadequate 'record of evaluation procedures used and the results', as required by 21 CFR 113.89, is a firm in which the only records supplied by the processing authority (which happened to be the firms corporate headquarters) to the processor was a statement that two deviations resulted in questionable processes, and the lot should be held 90 days; 100 percent examined; and any swells found should be submitted for further testing.

CFSAN notified the processing authority its' deviation evaluation report did not constitute a proper 'record of evaluation procedures used and the results', and the firms hold, sort and ship method of process deviation evaluation, was, by itself, not acceptable.

While CFSAN accepted the firm's policy of not providing its processing plants with all the data and information generated during the process evaluation, it found the processing authority's written communication to the plant lacking because it did not state that the deviations had been evaluated (in this case computer calculations and evaluations by their technical personnel), or indicate whether the product was commercially sterile, meets the requirement for the minimal thermal process, or is unsafe.

INSPECTIONAL CONSIDERATIONS: Investigators should not routinely ask for process establishment data (the data used to establish the scheduled process), or records of the evaluation procedures used for evaluating deviant processes. During an inspection you will routinely ask (by use of a FDA 482b) for written documentation from a processing authority which delineates the recommended scheduled process and the venting/come-up procedure. You may also request evaluation reports for deviant processes, which FDA is entitled to under the regulations.

If you have any doubts about the adequacy of the firms scheduled processes or procedures, or deviation evaluation, or if you question the qualifications of the processing authority, after discussing the matter with you supervisor, or LACF monitor, contact HFS-617.

If the firm is using someone other than a recognized processing authority, it may be necessary to obtain and review the following additional information. However, do not request this information unless you are instructed to do so by your supervisor:

1. Individual's name;
2. Individual's work affiliation (e.g., consultant, university, firm's employee, etc.);
3. The individual's academic and industrial experience related to thermal process work;
4. General procedures used to establish processes and/or evaluate deviations, such as an overall experimental plan for development of data, factors and variables considered, and range of experiments used;
5. Details of actual experimental methods used, including heat penetration and distribution data and microbiological data when appropriate;
6. Protocol for making conclusions based on experimental data;
7. 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 calculating the F_0 value;
8. The equipment used to perform the experiments including manufacturer, model number, state of repair, and other pertinent data;
9. The accuracy of the test instruments and other equipment, and the records showing that the instruments were routinely calibrated with an accurate standard;
10. Any other facts which have a bearing on the adequacy of the evaluations. where a processing authority who is not generally recognized as competent is involved, the EIR endorsement should specifically request a review of the information and data presented on the evaluation of the process deviations.

This information along with the EIR and all documentary materials (eg: recorder charts, processing records, etc.) should be forwarded by your district to the CFSAN for evaluation. In those cases where a processing authority who is not generally recognized as competent is involved, the EIR endorsement should specifically request a review of the information and data presented on the evaluation of the process deviations.

If a firm is under an order of need for a temporary emergency permit (see Emergency Permit Control Section), they are prohibited from distributing any products in interstate commerce until they obtain a permit, or until they receive advance written approval from FDA (21CFR 108.12). CFSAN will grant approval for product distribution into interstate commerce only upon an adequate demonstration that such food is free of microorganisms of public health significance. In those instances in which processing and production records are complete and there is no indication of the entry of potentially inaccurate information, FDA requires that all of the records for each lot in the possession of the processor be reviewed by a competent processing authority to identify deviations from the scheduled process, and that each deviant process be evaluated for public health safety. If evidence indicates previously distributed product may pose a potential health hazard, FDA may also require record review for all production lots which may be in interstate commerce. The results of these reviews and evaluations must be contained in a written document in a manner which certifies that all processing records for each production lot have been properly reviewed.

In the past CFSAN, has been amenable to other arrangements, by which another person (properly qualified) reviews the records, and then sends them to the processing authority for evaluation. Because these products are released in writing for distribution, CFSAN is very particular about the adequacy of record review and process evaluation.

CFSAN may also require additional heat penetration or heat distribution studies in cases where heating data does not encompass a certain critical factor, or where retort piping has been changed.

From: Office of Regulatory Affairs, Food and Drug Administration. (undated). Guide to Inspections of Low Acid Canned Food Manufacturers – 1, p 9-12. Washington DC

http://www.fda.gov/ora/inspect_ref/igs/lacfpt1/lacfpt109.html
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