Why Filings Were Introduced in the United States in 1973

IFTPS
Porto, Portugal
Stephen H. Spinak

History of Low-Acid Canned Food Regulations

1971 FDA proposed statement of policy-Petition filed by NCA

1973 GMP (Part 128b now 113) regulations published

1974 Emergency Permit Control Regulations (Part 90 now 108) published (included acidified)

1979 GMP Regulations (Part 113) implemented separate regulations for Acidified Food 108.25 & 114

21 CFR 108
Subpart B — Specific Requirements and Conditions for Exemption from or Compliance with an Emergency Permit

21 CFR 108.25 Acidified Foods

21CFR 108.35 LACFs

21 CFR 108 (Then Part 90) Subpart B — Specific Requirements...

Registration - 108.25(c)(1), (108.35(c)(1))

- Manufacturer must register within 10 days after starting production.
- Each processing facility must register.
- Processor must notify FDA no later than 90 days after production ceases.
- Registration and process filing required only if finished product enters interstate commerce.

21 CFR 108
Subpart B — Specific Requirements...

Parts 108.25(c)(2), Acidified (1979) & 108.35 (LACF)

- **Provide scheduled process information — including, information as necessary, conditions for heat processing, control of fill weight, particle size formulation, processing procedures, pH, salt, sugar and preservative levels**
- **Provide source and date of process establishment**
- **Each food in each container size**

21 CFR 108
Subpart B — Specific Requirements...

§108.35(c)(2) - Process filing :

Processor must provide the following for each LACF product and container size:

- **Processing method**
- **Type of retort or other thermal processing system**
- **Minimum initial temperature (IT)**
- **Processing times and temperatures**
- **Sterilizing Value (F_o) or other Equivalent Scientific Evidence**
- **Critical factors**
- **Source and date of process establishment**

21 CFR 108
Subpart B — Specific Requirements...

§108.35(c)(2)(ii) - Process filing

For Changes in a previously filed process by reducing IT, Process Time or Temperature, changing formulation, the container, or other condition basic to process adequacy - within 30 days of first use the processor:

- Increases in IT, Process time or Temperature must be filed if regularly scheduled
- Must provide a complete description of the modifications
- Must obtain and submit substantiation by a processing authority

21 CFR 108
Subpart B — Specific Requirements...

Process adherence and information -(Parts 108.35(c)(3) and 108.25(c)(3)) -

- (i) The processor must process in conformity with filed scheduled process.
- (ii) Process information availability — Processor must provide FDA with any information concerning processes and procedures which is deemed necessary by FDA to determine adequacy of process.

Providing such information does not constitute FDA approval.

Reasons for Requiring Filing

- To assure that scheduled processes were scientifically determined
- To assure that methods of process establishment and process calculations were adequate
- To assure that sterilizing values were sufficient
- So FDA could determine practices of the industry – product and equipment – to enable quick detection of widespread common problems

What Happens When Critical Factors are Not Considered - Lessons Learned from the Mushroom Crisis of 1973

- **Use of vibrating/tumbling filler without being addressed by heat penetration tests**
- **Fill weights exceeded**
- **Matting**
- **Slice thickness changes**
- **Fines**

What Was the Approach?

- **Product – Name, Form or Style, and Packing Medium**
- **Type of Retort or Other Processing System**
- **Process Time and Temperature**
- **Sterilizing Value (F_o) or Other Equivalent Value**
- **Critical Factors**
- **The source and date of the process establishment**

General Issues

The Sterilizing Value

Of possible concern are processes based on F values that are less than an F_o of 3. In these instances, a processor must submit data on the heat resistance of Clostridium botuIinum spores in the product.

Review of the Filing

- **FDA has heat penetration data it uses to scrutinize the filing. If it has concerns with the process it gives the firm the opportunity to provide its data.**
- **If you did not submit the test report with the original filing, they will ask you for it through a filing form inquiry letter or online with an email request.**
- **You respond and they review your response**

The Product and Process

"Regardless of the scientific method employed, a thorough evaluation of the results requires that detailed information on the product and process delivery conditions be provided. For example, a detailed description of the product, including critical factors, must be provided. Was it a commercial product, a laboratory prepared product, a simulated product, etc.? If the test product was different from the commercial product, a justification for its use should be provided. Also, information on container filling and closing equipment and procedures should be submitted, along with any critical factors such as fill weight, solids-to-liquid ratio, etc."

Heating Equipment and Conditions

"Regarding heating equipment and conditions, we expect the following to be submitted:

1. A description (including manufacturer) of the test apparatus.

2. Conditions during heating and cooling; e.g., type of heating and cooling media, heating-medium temperature, cooling-medium temperature, and pressure conditions.

3. Number of test containers and container dimensions.

4. Location and orientation of the containers in the processing apparatus, and the number of containers in the apparatus during a test, compared to the capacity of the processing apparatus."

Heating Equipment and Conditions

"Regarding heating equipment and conditions, we expect the following to be submitted:

5. Venting and come-up times (where applicable) and process time.

6. If an agitation process, the type of agitation and related information such as reel diameter and speed.

7. Information demonstrating the adequacy of heat distribution within the test apparatus."

Spore Performance Data

"For those process design methods which utilize calibrated bacterial spores, a complete description of the test program used to establish spore performance is essential In addition to species name and/or collection, the following information is needed:

1. Source of the spore suspension.

2. Heat-resistance test employed.

3. Temperatures at which tests were carried out and the number of replicate tests at each temperature.

4. Number of heating times at each temperature and number of replicates per heating time."

Spore Performance Data

"5. Initial number of spores per test unit.

6. Substrate (including concentration) in which spores were suspended during heating.

7. Description of the treatment of survivors.

Furthermore, a description of the treatment of the raw test data used to arrive at calibration results and a copy of. all results (e.g., the D value, the thermal resistance curve, and the indicated z value) that were used in determining sterilizing values should be submitted."

Heat Penetration Tests

"It is necessary to have information about the equipment used. This should include a brief description of:

1. **The thermocouples or other temperature-sensing elements.**
2. **The temperature-measuring unit.**
3. **The location of the sensing element in the test container, and the basis for selecting the location.**
4. **The relative location of the test containers in the heating apparatus.**
5. **The location of the sensing element used for measuring the heating-medium temperature."**

Heat Penetration Tests

"The raw time-temperature data should be furnished for each test container from the time steam is turned on until the end of cooling. If the data were analysed by the "Ball" method the resultant heating factors for each test container should be delineated.

Regardless of the calculation procedure used (for example, Ball. Stumbo, General Method), it is necessary to provide a description of the procedure and a copy of the calculations (or the data used) leading to the filed process.

If heat penetration tests were conducted using a heating apparatus other than the equipment used to commercially process a product, a justification of the applicability of the test data to commercial conditions should be provided."

Count Reduction

"1. Number of spores and volume of spore suspension per container.

2. With direct product inoculation, a description of how the spores were inoculated .into the product.

3. With spores in an impermeable carrier unit, a description of the location of the unit in the container.

4. Procedures used for recovering the spores from the product and for sample assay.

5. Treatment of controls; i.e., inoculated but non-heated containers.

6. Method used to determine sterilizing values, and the calculated sterilizing value for each test container. This information should include a sample analysis showing how the spore calibration data and the data from controls and heated containers are combined to yield each sterilizing value."

Inoculated Pack

"1. A description of the test program. This includes such information as the number of conditions evaluated, the number of replicate containers per test condition, and the-number of unheated controls.

2. The background microbial load of the test product.

3. Incubation conditions.

4. The method and criteria used to confirm growth.

For example, if swelled containers were used to determine growth, what constitutes a positive container? If sub culturing was used,a complete description including procedures used to identify the inoculated organism is needed.

5. Test results for each experimental condition, including the results of non-inoculated control containers, number of containers with confirmed growth and the estimated sterilizing value.

6.A summary of the interpretation of the results in support of the filed process."

When does the filing need additional data support?

- **Temperature distribution, heat penetration or microbiological data, or support drawings)**
- **Describe the requirement for attaching process source TD and HP documentation to filing for cascade, shower, trickle, steam water spray**

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- Began in 1988
- Load variations
- Stacking patterns
- Position of indicating devices often just after the heat exchangers

Note: Serious maintenance and cleaning problems have been found with these systems.

Summary

- The documentation has to be good because the process has to be right.
- FDA filings should be made anticipating the primary questions.
- The most important part of the documentation is the requirements for the user of the process.
- Have someone in your group review the documentation simulating an FDA review.