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The Process Authority Role as Impacted by FSMA

IFTPS 2013 Annual Meeting
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“Competent Process Authority”?

- The term has been used for years within the Low-Acid Canned Food industry for the person with the expert knowledge on thermal process establishment
- No definition has been given in any other FDA preamble or regulation



Federal Register July 23, 1976 – 21 CFR 128b

- Question on qualifications of “Competent Processing Authority” (FR, Vol 41, No. 143, page 30445)
 - “In the Commissioner’s opinion the technology for establishing an adequate process for a low-acid canned food is complex and generally learned only by practical experience in addition to formal training. **A competent processing authority must fully appreciate all the factors affecting the rate of heat penetration and must understand the need to use all features of food microbiology including the microbiology of canning.**”



Federal Register July 23, 1976 – 21 CFR 128b

- Cont'd (FR, Vol 41, No. 143, page 30445)
 - “Some special staff members of the following organizations possess such a competence: Laboratories of container suppliers, canning industry trade associations, universities, canning firms, consultants, and government.”



“Competent Process Authority”?

- Verbally people have used the term loosely
- No other FDA regulation uses the term “Competent Process Authority”
- Within FDA over the years the term has been used specific to the low-acid canned food industry

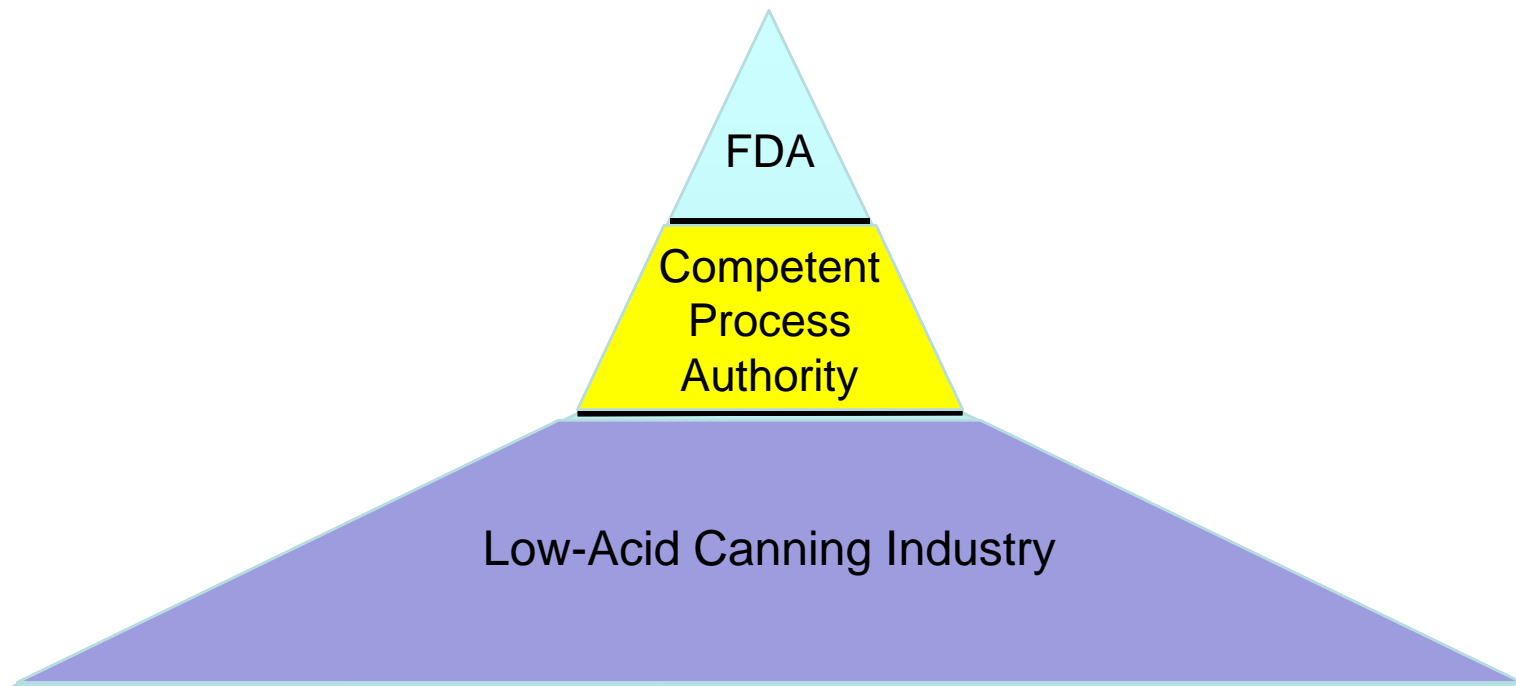


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Role of “Competent Process Authority”





Benefits to LACF Model

- FDA (*resource restricted*) interacts with small group of knowledgeable individuals
- Small group (*fee based*) of Competent Process Authorities (PA) can interact with much larger food processing industry
- Industry receives more consistent understanding of FDA expectations and requirements



Proposed Preventive Controls Rule

- Definition of a “Qualified Individual” – 21 CFR 117.3
 - “A person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.”



Proposed Preventive Controls Rule

- The “Qualified Individual” – 21 CFR117.155(a)
 - Do or oversee the preparation of the food safety plan
 - Validate the preventive controls
 - Review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions
 - Perform reanalysis of food safety plan
 - The same person does not need to perform each of these



Proposed Preventive Controls Rule

- The “Qualified Individual” – 21 CFR117.155(b)
 - Successfully completed training in the development and application of risk-based preventive controls at least equivalent to FDA standardized curriculum
 - Or, qualified through job experience to develop and apply a food safety system if experience is equivalent to FDA standardized curriculum
 - May or may not be employee of facility



The PA in a FSMA World

- As it stands now, the role of the PA is not changing – LACF specific
- If the PA wants to take on the responsibility of the Qualified Individual (QI) there will be an additional education expectation
- The QI may function more as a manager, with the wide-ranging role needed for implementation of the food safety plan



The PA in a FSMA World

- We are still dealing with a proposed rule
- Changes in definitions can happen for the final rule
- With the addition of a food safety plan requirement to deal with chemical, physical, and radiological hazards for LACF products the PA may be expected to take on the role of the QI