

Questions to Consider When Evaluating Studies of Alternative Handwashing Approaches

- a. Primary Question
 - Is this a substitute for handwashing, and under what conditions?

- b. Methodology Questions on Submitted Study
 - What were the objectives, control measures, outcomes, etc. of the referenced study?

 - What was the sample size of the study referenced? Was there a control group?

 - What are the limitations of the study referenced (For example, can the results be broadly applied to all sanitizers or are there limitations? Have studies also tested other formulations / brands?)

 - What is the efficacy of the method?

 - Has this process been studied with additional foodborne pathogens and the ability to reduce these pathogens on hands?

 - Evaluation of a process against Norovirus? Is there a clinical study? “In vivo” study? Surrogate? What is the desired efficacy? (NDA issue)

- c. Behavioral Questions on Submitted Study
 - Has this process researched for ease / frequency of use (e.g., will employees use the method?), and undesirable side effects (e.g., rashes / dry, cracked skin;)

 - Are there any behavioral studies to ascertain if this process is appropriately and consistently used by foodservice personnel in the field? Any difference in compliance rates in a variety of settings (major food company vs. mom and pop)?

- d. Questions on the Submitted Study
 - Who funded the referenced study?

 - Has this study been replicated by academia or additional independent third parties without a fiscal or commercial interest?

 - Has this study been replicated in actual foodservice settings?

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e. Other

- Are there any legal issues surrounding acceptance of the study/terminology that would affect acceptance by CFP (ex. copyright, trademark, peer review process for the publication)?
- What was the discernment process / criteria used by any agencies that have accepted this process?
- Are there studies that have proven or established the efficacy of alternative methods of cleansing hands?
- Research must be done to specify the efficacy of each method.
- The questions listed in the 2010-2012 CFP Hand Hygiene Committee white paper ["Scientific Regulatory and Behavioral Considerations of Hand Hygiene Regimes"](#) should be part of any research for an alternative handwashing process.
- Does the "new" process give a 2-log vegetative cell and virus reduction?
- Chemicals (sanitizers) depend on contact time on the hands, therefore time must be considered.
- When would the process be considered? When water is not available? Always?
- Is there sufficient scientific evidence to support a recommendation to the Food Code?