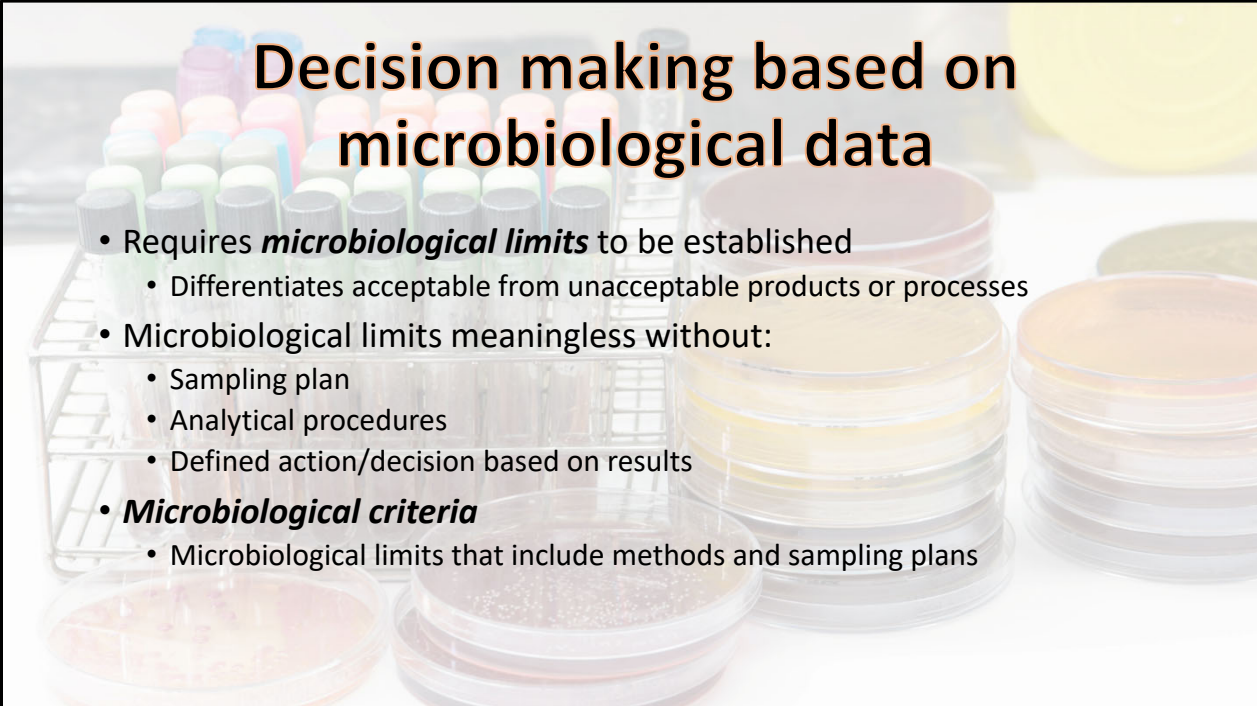




Welcome everyone to the second webinar in our series “Integration of food quality assurance programs with FSMA preventive control compliance.” This webinar series is targeted to small processors to aid in FSMA implementation by highlighting the overlaps between the regulation’s requirements and what processors are already doing as part of their QA program. The webinar series is made possible by a grant from the USDA’s Food Safety Outreach Program. This webinar will focus on Microbial Testing and Standards. I am Erin DiCaprio, food microbiologist, from the University of California Davis Department of Food Science and Technology and I will be the speaker for today’s webinar. We are using Zoom as the platform for this webinar series. We will be muting all participants and encourage you to ask questions via the chat function. Your questions and comments will drive changes in the content of this webinar for future offerings. Following the conclusion of the webinar today you will receive an email with a link to a survey. Please take the time to complete this survey, it will help us to determine ways to improve this webinar in the future.



## Decision making based on microbiological data

- Requires **microbiological limits** to be established
  - Differentiates acceptable from unacceptable products or processes
- Microbiological limits meaningless without:
  - Sampling plan
  - Analytical procedures
  - Defined action/decision based on results
- **Microbiological criteria**
  - Microbiological limits that include methods and sampling plans

One of the questions that always arises is, “What is an acceptable level for these microbial tests in my product?” Unfortunately, establishing this microbial limit without associated methods and sampling plans is a frivolous endeavor. As I mentioned a test method must be matched to your food type. In addition, you have to determine where you will be sampling and the frequency at which that sampling will occur. Finally you must establish what happens if you have a failing result. For example, if we have an APC above our microbial limit on a cleaned and sanitized food contact surface this may result in re-cleaning and sanitizing that surface before product is run on that line. Or, if we have a positive indicator test post processing in our final product this may initiate reprocessing or rework on this product. When we have microbiological limits that include the sampling plan, analytical procedures, and the define action or decision based on the results this is termed microbial criteria. Therefore, the question we should be asking “How can I establish the microbial criteria for my product?”

## Microbiological criteria

- Specify the number of sample units to be collected
- Analytical method
- Number of analytical units that should conform to the limits
- Established for quality and safety
- Used in setting standards, guidelines, and purchase specifications

When establishing your microbial criteria you want to make sure you include the type of sample you are collecting (for example environmental swab, or x grams of product) and the number of samples you will be collecting. You would also include location for environmental sampling. The analytical method must be included and needs to be a scientifically validated method. You as a processor must establish how many of your test results must fall within the limit you have set for the specific microbial test. For example, if you are using APC to verify cleaning and sanitation for a food contact surface you might set a threshold of <500 CFU/mL as acceptable. You may also establish that 90% of your samples must conform to this limit, so if you collect 10 samples one of those samples can have an APC above 500 CFU/mL and you will still have an acceptable results for your microbial criteria for cleaning and sanitizing this surface. You establish these criteria for both microbial quality and safety reasons and microbial criteria are also important due to regulations and buyer requirements.

## Analytical methods

- Must know the method used when communicating microbiological criterion
- Must be matched for microorganism and food type
- Sources of scientifically valid methods for examination of food:
  - International Standards Organization (ISO)
  - FDA Bacteriological Analytical Manual (BAM)
  - American Public Health Association (APHA) Compendium of Methods for the Microbial Examination of Foods

Determining the appropriate test or analytical method is very important. As previously mentioned the analytical method of choice must be validated for the target organism and food type. A method developed for one food type may not work in a different food matrix. There are several sources of validated methods including: ISO, BAM, APHA, and others. A critical factor to understand when reporting and interpreting microbial test results is the unit in which the result is reported. Common units include CFU (colony forming unit) / x grams or x milliliters and Most Probable Number (MPN) / x gram or x milliliters. Other tests may simply give you a presence or absence result. Certain regulations may have specific units in which they require results to be reported, so make sure that you understand these requirements if they apply to your product. Also understand that each analytical method has a limit of detection, or a level of microorganism below which the test will be negative even though the microorganism is present. This means that there is never a true zero test result. Some results will be reported as below detection limit, often the case if the test is quantitative. Remember a “negative” does not mean zero, it could be there is none of the target organism in the sample or just that the level of the target is below the detection limit.

## Terminology related to acceptance criteria for microbiological testing

- Microbiological standards:
  - International, national, or regional laws
- Microbiological specification:
  - Between vendor and buyer
- Microbiological guidelines:
  - Internal advisory criteria

Now we will get into some of the terminology related to microbial testing. Note that these terms are used interchangeably in many situations. Microbial standards refers to regulations that require that define a microbial limit. A microbial specification is a microbial limit that is set between a vendor and a buyer. Microbial guidelines are often set internally by a processor or are established by a specific industry.

## Microbiological standards

- Exceeding a standard for a pathogen may require recall
- Legal acceptance criteria
- Zero tolerance
  - Shiga-toxin producing *Escherichia coli* (STEC) in ground beef
  - Any pathogen in ready-to-eat foods



Microbiological standards in the United States are established by the FDA and USDA for specific high risk food types. Exceeding an FDA or USDA microbiological standard will require a recall. These are essentially the legal acceptance criteria for your product to enter commerce in the US. Many of these microbiological standards are “zero tolerance” for pathogens. Examples include STEC in beef and *Listeria monocytogenes* in ready-to-eat foods. This means if you have any type of positive results for these pathogens in these products that you must recall.

## Microbiological specification

- Failure to meet vendor specifications can lead to product rejection
- Customer acceptance criteria
- Dependent on the processing of the product



Microbial specifications again are those microbial limits set between a buyer and supplier. As I'm sure you're all aware, failure to meet your buyer requirements can lead to product rejection and potentially loss of that buyer. Again these microbiological specs are going to be dependent on the product and type of processing. For example, pasteurized or cooked products typically have microbiological specifications that are low for APC, EB/coliforms, lactic bacteria, yeast, and mold. Ready to eat fermented foods typically do not have microbiological specifications for APC or lactic acid bacteria, we expect high levels, but EB, coliforms, yeast, and molds should be low. In dried ready to eat products such as spices APC, Lactic acid bacteria, yeast, mold will be higher due to the processing methods. However, EB/coliforms should still be relatively low. Specifications for raw products, such as produce, are rare but some exceptions exist. Overall the buyers' needs drive specification limits. Lower microbial load ingredients may drive a higher price and negotiations are common. The microbial load can also drive a buyer to select one lot over another.



## Microbiological guideline

- Internal acceptance criteria
- Established by a processor, trade association, or government
- Serves as an alert that remedial action should be take

Microbial guidelines are internal acceptance criteria established by a processor or trade association. In the yogurt example provided by Luxin in webinar 1, there was a requirement established by the National Yogurt Association for labeling a yogurt product as “contains live and active cultures”. This microbial guideline for yogurt is 100 million active cultures/g of yogurt.

## Summary

- Microbial criteria include microbial limits, sampling plans, analytical methods, etc. and are used for product “acceptance”
- Analytical methods must be matched to target microorganism and product
- Microbiological standards: legal acceptance criteria
- Microbiological specification: set between a buyer and supplier
- Microbiological guideline: internal acceptance criteria



This information is provided by the authors in good faith, but without warranty. It is intended as an educational resource and not as advice tailored to a specific operation or a substitute for actual federal or state regulations and guidance from FDA or other regulatory agencies. We will not be responsible or liable directly or indirectly for any consequences resulting from use of information provided in this document or resources suggested in this document.

This presentation and recording are covered by the University of California Copyright Ownership Policy and were generated by Dr. Erin DiCaprio as Scholarly work.



United States Department of Agriculture  
National Institute of Food and Agriculture

The development of this material was supported by the National Institute of Food and Agriculture, U.S. Department of Agriculture, under award number 2020-70020-32263. USDA is an equal opportunity employer and service provider. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of the U.S. Department of Agriculture.