Q&A Boot Camp 2.22.24

I have a question on fermenting. We have a place wanting to make their own pineapple vinegar by adding pineapple, water, and brown sugar. No starter culture. How could they do this safely?
Would be safe if initial pH must be ≤ 4.20 and final pH is ≤ 3.3. If that is not the case, we would need to look deeper into it (I would be happy to discuss!).

So, when potatoes are green like the picture, should we throw them away? What about when you have potatoes and they start sprouting roots from them, are they good to eat or throw those away as well?
Glyalkaloids concentrate on the green parts of the skin, so it is safe to consume the potatoes if you remove the skin. That's what I do and encourage anyone to do to avoid food waste, but its also what the USDA says 😊

Why are ruminants exempt from nightshade poisoning?
Their digestive system is completely different from ours. In their case, the food is fermented in the rumen where many of these compounds are broken down by microorganisms.

Can someone give more info on nutritional yeast and pathogens of concern
As a dry ingredient, Salmonella is a pathogen of concern.

Is drying the same as dehydration?
Yes, however, it seems that when the manufacturers use the term "dehydration" they are trying to confer that they are using a low-heat process. The important thing is to remember that if the food product is at an internal temperature below 135ºF they must have pH or Aw as a barrier against pathogenic growth.

Can you speak on the sun drying process and validation for those products?
We would require a step to control pathogens before the beginning of the drying process. This could be done by dipping the vegetables into boiling water or a sanitizer solution.

would the HORCHATA process (soaking rice) would be a problem or would it be safe to be soaked in the refrigerator?
B. cereus, if present, would be able to grow if temperature is >4ºC. Refrigeration to ≤ 4ºC would control that hazard. If proper microbial studies are done you would be able to establish how long rice can be safely soaked at other temperatures, but these studies are expensive. It is also possible that studies have already been done and information is available in ComBase.

best buy vs use buy
Unfortunately, we don't have standardized language for shelf life. We recommend "Best By" for products that will not sustain growth of pathogens (ex, pH ≤ 4.2 or Aw ≤ 0.85). "Use By" indicates that after the shelf life ends the product may be hazardous (i. e., products that are "refrigerated for safety).

Q: **When would ceviche be considered a special process?**
A: Processes in which any raw protein (such as fish or beef) that is to be considered **ready-to-eat (RTE)** in its raw state are acidified and held longer than the 7 days allowed for TCS RTE foods, or if they are to be considered shelf stable, would be considered a special process.

Product assessment should confirm that the protein has reached pH less than 4.2 (e.g., 4.1 or lower), and operator must document pH of each batch. In the typical scenario, the product would not be "packaged," so Interaction Table B of the FDA Food Code applies. When refrigerated, and stored no more than 7 days, not a special process.

Q: **What if you have an operator making shrimp ceviche in house and only uses the lime, no cook step. If the shrimp is farm raised vs coming from the ocean, would parasite destruction still be required? or like farm raised salmon and some other fish, would it be considered exempt too?**

A: The FDA Food Code, Section 3-402.11 applies to all "fish" as defined by the Food Code including shrimp. Subsection A provides the time and temperature parameters for freezing as the method of parasite destruction. Subsection B(4) provides the required conditions by which aquacultured shrimp can be exempted from parasite destruction requirements. Section 3-402.12(B-C) allows a supplier letter of guarantee or purchasing agreement to substitute for meeting the freezing requirements; this record shall be maintained for 90 calendar days beyond the time of sale or service of the product.

Q: **Are juices bottled in non-hermetically sealed plastic jar a special process?**
A: The presence of a hermetic seal would be associated with a pasteurization process, which would require a process letter from a Processing Authority and approval from the Regulatory Authority as a special process. FDA Food Code Section 3-404.11(B) requires that "Juices packaged in a food establishment shall be . . . Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance . . ." with the consumer advisory language provided in 3-404.11(B)(2), as specified in 21 CFR Part 101.17(g). This option does not involve a special process, but compliance should be confirmed.

Q: **Do you have any tips/tricks to get retail food establishments to complete all this documentation?**

A: 1.) Stop the process until approved, and advise the PIC that the process may require review and approval of a safety plan. Do not tell the PIC they need a HACCP plan – that term and the concept are scary to the vast majority of retail food operators because they have never been exposed to HACCP. 2.) Templates that provide the complete format and required guidance to assist the operator in providing the required information are a tremendous help to the operator. However, a "triage call" from the Special Process Coordinator or Variance Committee representative to determine the appropriate guidance is essential to put the correct template in the PIC's hands. 3.) A mentoring approach to the review process is also very helpful, in which the review comments are discussed with the PIC by a qualified HACCP reviewer to be sure they understand the process requirements and the required corrections. 4.) Involve the inspector in the review process. 5.) Encourage the PIC to consider the HACCP reviewer/variance committee as a resource to guide them in successfully implementing their plan. We must emphasize our role as a resource – our concern is that the PIC must commit to conducting the process under an approved plan, rather than hiding the process and continuing to use it potentially without proper safety controls.

Q: **What do you do in your jurisdiction when they fail to maintain all these requirements?**

A: Failure to follow the requirements of a previously approved HACCP plan results in an OUT mark for that item ("Compliance with variance, specialized process, reduced oxygen packaging criteria, or HACCP plan") in the inspection. The inspector itemizes the failed criteria in the

inspection report and provides guidance (education/re-education as “compliance assistance”). In some cases, especially when there are repeat violations or when the establishment has modified the process from what was approved, the Special Processes Team or Variance Committee may become involved to provide further education and guidance. Follow the Food Program policy on enforcement actions that may be required.

Q: **Does freeze drying require a HACCP plan and variance?**

A: At minimum should have GMP. Definitely recommend HACCP plan and variance if product is TCS, especially if dehydrating or freeze-drying TCS products. See Question 7.

Q: **Have you seen a situation in which TCS foods that were out of temperature for more than 4 hours were used in a freeze dried product? Did consumers become sick?**

A: Research studies have found that dehydration (including freeze drying) is not enough to kill pathogens, especially with Salmonella. Pre-drying treatments can be used to assist in decreasing pathogen load. One study reported that between 1958 to 2017 there were 41 foodborne illness outbreaks related to dried foods. Salmonella was most often implicated (14 from powdered infant formula, 11 dried meat products, and 10 dried spices).

Q: **How do you all feel about caramel apples being TCS? Some jurisdictions have them as TCS as they do have history of listeria outbreaks, some seem to not.**

A: At issue here is the fact that the apple is dipped into the hot caramel, which is typically above 230ºF. The apple may therefore be considered “heat treated plant food”, making it a TCS RTE product. However, that brief heating of the apple is not likely to cause a significant increase in the apple’s internal core temperature. This contrast seems to be the basis for different decisions on this question at jurisdiction level.

Q: **Any information on butter powder?**

A: Butter powder would be a non-TCS product due to greatly reduced **water activity (Aw)**. When any food is dried to the point that it can be reduced to a free-flowing powder, the Aw value will be very low, making it a non-TCS product according to the FDA Interaction Tables.

Q: **Where can we find the TCS study Jon mentioned?**

A: This question is referring to the study delivered by the Institute for Food Technology to FDA in 2001, entitled “*Evaluation and Definition of Potentially Hazardous Foods*.” Here is the link to that study: https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-Potentially-Hazardous-Foods.pdf

Q: **Cricket guacamole would not be heated before service. Do we need letters from crickets providers about parasite destruction or information about how the crickets are raised?**

A: Crickets would need to be sourced from an approved supplier that produces crickets for human consumption. I would recommend that they be roasted before adding to the guacamole to provide a kill step.

Q: **Would the fermentation process for Injera, which uses the "Tef" grain, be a special process?**

A: Fermentation processes as a whole are considered special processes because the combination of fermentation ingredients, temperature and time must allow the fermentation organisms to out-compete any pathogens that may be present. Injera is produced over about 5 days fermentation by lactic acid bacteria, which produce acid and reduce the pH of the product. The pH must quickly be reduced below 5.3 to prevent toxin formation by *Staphylococcus aureus*; the final pH is typically below 4.0 and the product is fried or baked into a flatbread. Naan and dosa are similar flatbreads produced primarily by lactic acid bacteria fermentation.

Q: **When thawing frozen ROP fish per manufacturer directions, does the fish (often tuna, salmon) have to be removed from packaging or can the packaged simply be pierced?**

A: The position FDA expressed at the Conference for Food Protection in April, 2023 was that the fish must be completely removed from the package for thawing. FDA expressed the concern that if the ROP package is simply "pierced" or "opened," pockets of reduced oxygen may exist in the package that could present a hazard.

Q: **Could ROP fish still be considered safe if being held at 38F or below?**

A: The primary hazards in fish are *Clostridium botulinum* Types E and non-proteolytic types B and F – these are the marine strains that can multiply and produce toxin as low as 38°F. Because of the serious nature of the hazard, FDA has required that the product be frozen while in ROP packaging to provide a wide margin of safety.

Q: **Is C. Bot contamination for smoked fish a risk only in ROP packaging? Or is it for any smoked fish?**

A: C. Bot grows when it is in an environment that is low in oxygen, has a pH greater than 4.6 and water activity greater than 0.88.

Q: **For the sous vide, it was mentioned to not let "come up time" exceed 6 hours. Where does it state that?**

A: This information is found in the FSIS Cooking Guideline for Meat and Poultry Products, (Revised Appendix A), December 2021, beginning at page 23. Here is the link to that resource: https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf#page=23

Q: **What is the special tape/thermometer to measure the internal temperature of the product in the bag without damaging the bag (compromising the vacuum)?**

A: Sous vide temperature monitoring kits can be found in an online search. What is necessary is self-sealing foam tape and a needle thermocouple probe. Using these together allows the probe to be inserted through the foam tape into the center of the product without compromising the vacuum. There are also applications (apps) that allow the data from a Bluetooth thermocouple to be monitored and recorded on a cell phone through the entire come-up time, cooking and cooling phase to provide a complete electronic record that can then be save to computer for the required more permanent record. The same kit can also be used in ROP cook-chill processes to monitor cooling.

Q: **As per the FDA Food Code 3-502.12, raw meats and poultry can be vacuum packaged for up 30 days at 41°F. Is this applicable to plain raw meats only? Many operators like to add spices such as salt, pepper, paprika, and even marinades before they vacuum package it for flavor purposes. Does adding spices like salt and pepper affect the competing organisms of raw meats and poultry? Will the 30-day shelf-life no longer be applicable for these products?**

A: To provide context for the answer: FDA Food Code 3-502.12(B) requires that ROP packaged raw meat products must meet at least one of four characteristics: Aw of 0.91 or less, pH of 4.6 or less, commercially cured by a USDA-inspected processing plant in compliance with 9 CFR 424.21, or have a high level of competing organisms. Marinades are typically rather acidic (generally pH <4.0), and they both provide flavor and help tenderize the meat. Marinades may be commercially processed as acidified foods (thermally processed), or may be ready made in-house (no thermal process, so potentially higher microbial load). If dry spices are used instead of a liquid marinade, that would typically be a dry rub, even if just pepper and salt, but may also include other seasonings such as rosemary, thyme, etc. Those herbs would add their own populations of competing bacteria. The ROP environment helps to infuse the meat with flavors of the seasonings and marinades; refrigeration must still be maintained. The answer to this question is that even with the added marinade or dry seasonings, this process still meets characteristics of the ROP process described in 3-502.12(B), and no variance would be required.

Q: **What do we know about the production and product Ghee?**

A: Ghee and clarified butter are similar. Butter is heated gently to simmer until all water is cooked off. In the case of ghee, the product is then lightly caramelized. It is non-TCS because water activity is greatly reduced, so it is shelf stable.