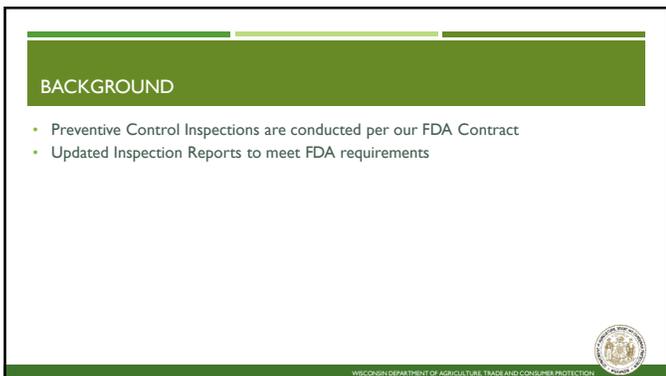




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WHAT TO EXPECT FROM DATCP STAFF

- PC Inspections will be conducted by at least 2 staff members
- Copies of Food Safety Plans
 - (Chapter 97.12 Enforcement – “The department and its agents may also... examine and copy relevant documents and records and obtain photographic and other evidence needed to enforce this chapter.”)
 - Including anything that 21 CFR 117 requires to be written
 - Hazard Analysis
 - Preventive Controls (process, sanitation, allergen, supply chain)
- Asking staff to leave all copies at the plant once inspection is concluded



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FEEDBACK FROM PREVIOUS INSPECTIONS

- Hazard Analysis
 - 21 CFR 117.130 (b) requires identification of hazards
 - Using ingredients and finished product use Table 1A – Biological Hazards; 2A- Chemical Hazards; and 3A - Process Hazards to identify any hazards associate with process.



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EXAMPLE: UNSALTED BUTTER – INGREDIENT CREAM

<ul style="list-style-type: none"> - Biological Hazards <ul style="list-style-type: none"> - Bacillus cereus - Pathogenic E. Coli - Salmonella spp. - L.monocytogenens - S.aureus - Campylobacter spp. (cream) 	<ul style="list-style-type: none"> - Chemical Hazards <ul style="list-style-type: none"> - Drug residue (cream) - Heavy metals (cream) - Industrial chemicals (cream) 	<ul style="list-style-type: none"> - Process Hazards <ul style="list-style-type: none"> - Bacterial pathogen survival of a lethal treatment - Bacterial growth and/or toxin formation due to lack of time/temperature control - Recontamination with environmental pathogens - Undeclared allergen – incorrect label - Undeclared allergen – cross contact - Metal
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FEEDBACK FROM PREVIOUS INSPECTIONS

- Hazard Analysis
 - 21 CFR 117.130 (c) (1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls
 - 21 CFR 117.130(c)(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:
 - (i) The formulation of the food; (ii) The condition, function, and design of the facility and equipment; (iii) Raw materials and other ingredients; (iv) Transportation practices; (v) Manufacturing/processing procedures; (vi) Packaging activities and labeling activities; (vii) Storage and distribution; (viii) Intended or reasonably foreseeable use; (ix) Sanitation, including employee hygiene; and (x) Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).



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FEEDBACK FROM PREVIOUS INSPECTIONS

- Determining whether a PC is needed
 - If a process control can be applied at a point or step in the food production **process to prevent or eliminate the food safety hazard, or reduce it to an acceptable level**, you should classify the point or step as a Preventive Control.



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 May 5, 2021

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