



Public Health Microbiology FoundationSM

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Re: Results of Analysis and Process Authority Letter, Food Processing Support Consultation of Public Health Microbiology FoundationSM, Nashville, TN

CC: *The Elderberry Lady of TN*

November 22, 2022

Ms. Teresa Kurowski,

Here are the results of the **equilibrium pH analyses** for your products:

The Equilibrium pH Results (mean ± SD): Food Processing Support Consultation of Public Health Microbiology Foundation*					
The Elderberry Lady of TN	Batch 1**	Batch 2	Batch 3	Average	Range (95% CI)
Elderberry Dudes Honey Mustard	3.56 ± 0.1	3.77 ± 0.0	3.78 ± 0.0	3.70 ± 0.1	3.61 to 3.79
Elderberry Syrup	4.13 ± 0.1	4.16 ± 0.0	4.17 ± 0.1	4.16 ± 0.1	4.10 to 4.21
Sip & Salad Elderberry Vinegar	4.15 ± 0.1	4.24 ± 0.0	4.04 ± 0.0	4.14 ± 0.1	4.07 to 4.21

*<https://publichealthmicrobiology.education/food-processing-support> **Each value is mean ± standard deviation obtained from three independent instrumental replications after calibration and temperature compensation for 25 °C. ^Confidence interval composed at type I error level of 5%

Here are the results of the **water activity analyses** of your products:

Water Activity Results (mean ± SD): Food Processing Support Consultation of Public Health Microbiology Foundation*					
The Elderberry Lady of TN	Batch 1**	Batch 2	Batch 3	Average	Range (95% CI)
Elderberry Dudes Honey Mustard	0.806 ± 0.00	0.806 ± 0.00	0.811 ± 0.00	0.807 ± 0.00	0.805 to 0.810
Elderberry Syrup	0.950 ± 0.00	0.942 ± 0.00	0.937 ± 0.01	0.943 ± 0.01	0.937 to 0.950
Sip & Salad Elderberry Vinegar	0.936 ± 0.01	0.944 ± 0.00	0.938 ± 0.00	0.939 ± 0.01	0.935 to 0.944

*<https://publichealthmicrobiology.education/food-processing-support> **Each value is mean ± standard deviation obtained from three independent instrumental replications after calibration and temperature compensation for 25 °C. ^Confidence interval composed at type I error level of 5%

Metrics used for evaluation: (Table is from Publication of Busta et al., 2003*)

Table A—Control of spores: Product treated to control vegetative cells and protected from recontamination.

Critical a _w values	Critical pH values		
	4.6 or less	> 4.6 to 5.6	> 5.6
0.92 or less	Non-TCS	Non-TCS	Non-TCS
> 0.92 to .95	Non-TCS	Non-TCS	?
> 0.95	Non-TCS	?	?

Table B—Control of vegetative cells and spores: Product not treated or treated but not protected from recontamination

Critical a _w values	Critical pH values			
	< 4.2	4.2 to 4.6	> 4.6 to 5.0	> 5.0
< 0.88	Non-TCS	Non-TCS	Non-TCS	Non-TCS
0.88 to 0.90	Non-TCS	Non-TCS	Non-TCS	?
> 0.90 to .92	Non-TCS	Non-TCS	?	?
> 0.92	Non-TCS	?	?	?

* Busta, F.F., Bernard, D.T., Gravani, R.B., Hall, P., Pierson, M.D., Prince, G., Schaffner, D.W., Swanson, K.M., Woodward, B. and Yiannas, F., 2003. Evaluation and definition of potentially hazardous foods. *Comprehensive reviews in food science and food safety*, 2(2), pp.8-14.

** F. Breidt, K.P. Sandeep, and F.M. Arritt. 2010. Use of linear models for thermal processing of acidified foods. *Food Protection Trends* 30:268-272. And, 2017 FDA Food Code *** Breidt, F., Kay, K., Osborne, J., Ingham, B. and Arritt, F., 2014. Thermal processing of acidified foods with pH 4.1 to pH 4.6.

Based on the information received and results of the analyses for the samples from three different batches you provided, it is concluded that product “**Elderberry Dudes Honey Mustard,**” from your company is considered as non-TCS commodity and is further considered as formulated acid food (acidified food with small amount of low-acid ingredients) with equilibrium pH <4.0 and thus requires to be manufactured under the regulations 21 CFR 114, 21 CFR 117, and 21 CFR 108.25. The products “**Elderberry Syrup,**” and “**Sip & Salad Elderberry Vinegar,**” from your company are considered as TCS commodities, thus requiring refrigeration to be manufactured under the regulations 21 CFR 117.

For the “**Elderberry Dudes Honey Mustard**” product, to ensure the safety of your consumers, your products should be heated to >185 °F and this temperature should be maintained for at least 30 seconds. Considering that pH values of your product is <4.0, this time and temperature combination is recommended to ensure 5-log reduction of common vegetative bacterial pathogens^{**}. Additionally, your product containers would need to be preheated to 178 °F (or sanitized by another validated method) and the product would need to be hot-filled at a minimum temperature of at least 178 °F, followed by 60 seconds inverted hold at this temperature^{**}. These will result in an estimated z value (°F) of 19.5^{**}.

For the “**Elderberry Syrup,**” and “**Sip & Salad Elderberry Vinegar**” product since they have pH values of >3.3, it requires heat treatment to ensure destruction of vegetative pathogenic bacteria^{**}. To ensure the safety of your consumers, these two products thus should be similarly heated to >185 °F and this temperature should be maintained for at least 30 seconds. This time and temperature combination is recommended to ensure 5-log reduction of common vegetative bacterial pathogens^{**}. Additionally, your product containers would need to be preheated to 178 °F (or sanitized by another validated method) and the product would need to be hot-filled at a minimum temperature of at least 178 °F, followed by 60 seconds inverted hold at this temperature^{**}. These will result in an estimated z value (°F) of 15.6^{***} (5-log reduction of non-typhoidal *Salmonella*). **I would strongly recommend you develop processing logs to monitor and document temperature values of all batches you prepare.**

The above-referenced procedure could destroy vegetative bacteria, and common molds and yeasts in your products, however, it is unable to eliminate heat-resistant molds and endospores of bacteria such as *Alicyclobacillus* and *Bacillus coagulans*. Spoilage challenges associated with these microorganisms could be minimized by adherence to the SSOP and cGMP articulated in the above regulations. Additionally, I recommend obtaining PC QI status by attending a workshop with a curriculum that is recognized as adequate by the U.S. Food and Drug Administration and following the best practices articulated in the workshop to prevent, eliminate, or reduce the risk of microbial, physical, and chemical hazards in your operation. Conducting a shelf-life study is my other recommendation to ensure evidence-based determination of your products expiration date.

It is noteworthy that your product is considered as a ready-to-eat (RTE) commodity and thus special considerations are needed to ensure your process can eliminate cross-contamination with microbial pathogens and cross-contact with allergens to ensure the public’s health. Environmental monitoring is an important aspect for production of RTE commodities like your products. Additionally, since your current facility might have residue of main allergens of public health

* Busta, F.F., Bernard, D.T., Gravani, R.B., Hall, P., Pierson, M.D., Prince, G., Schaffner, D.W., Swanson, K.M., Woodward, B. and Yiannas, F., 2003. Evaluation and definition of potentially hazardous foods. *Comprehensive reviews in food science and food safety*, 2(2), pp.8-14.

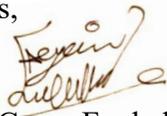
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concern, I recommend incorporating this statement in your labels in addition to efforts articulated in the above regulations to minimize risk of allergen cross-contact in you operation:

“Processed in a facility that also processes food containing milk, egg, fish, peanut, shellfish, soy, tree nuts, wheat, and sesame. May contain traces of milk, egg, fish, peanut, shellfish, soy, tree nuts, wheat, and sesame.”

I wish you further success in business development and for ensuring the public’s health during your future endeavors. Please take the liberty in contacting my foundation for interpretation of these results and anytime you would need further support and testing for your operation.

Best wishes,



Dr. Aliyar Cyrus Fouladkhah, PhD, MS, MPH, MACE, CFS, CPS

Founding Director, Public Health Microbiology Foundation

Disclaimer: This letter is granted to assist an entrepreneur in meeting the regulatory requirement of interstate and intrastate food commerce. The letter and the analyses results are provided based on the information provided to the laboratory by the entrepreneur. This letter could be used solely for regulatory purposes and could not be considered as an endorsement of the product(s) or for business development purposes. Thus, dissemination of the letter to any non-regulatory agencies is strictly forbidden. Public Health Microbiology Foundation is not responsible for any future liabilities associated with the sale and consumption of the product(s) listed in this letter. The information, advice, and opinions provided by Public Health Microbiology Foundation represent the best judgment of the Foundation at that time but should not be considered legal advice on any local, state, federal, or international regulation or statute. We encourage you to contact the applicable regulatory agency and/or qualified attorney to confirm the information presented in this correspondence.

* Busta, F.F., Bernard, D.T., Gravani, R.B., Hall, P., Pierson, M.D., Prince, G., Schaffner, D.W., Swanson, K.M., Woodward, B. and Yiannas, F., 2003. Evaluation and definition of potentially hazardous foods. *Comprehensive reviews in food science and food safety*, 2(2), pp.8-14.

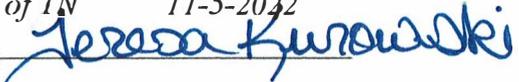
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Product Description Form
Food Processing Support Center
Public Health Microbiology Laboratory



This form is designed for the entrepreneurs to declare their product name, detailed ingredients, allergen profile, and production description. Before submitting the form please also sign the honor code. If you have multiple products, please submit one sheet per product. Please type your answers for each product in the space provided. If you need more space, please use an additional page.

Honor Code: *I certify that the information provided is accurate and reflects the product that I submitted for testing and evaluation to the food processing support center.*

Teresa Kurowski The Elderberry Lady of TN 11-5-2022


 (Legal Name) (Company) (Signature) (Date)

Product Name, container material, net weight of the product, serving size per container.	Current Location of Manufacturing	Complete List of Ingredients	Allergens in the Product and production facility*	Description of Production** (Please include how many products are prepared per batch using the formulations/recipe you provide here)
Elderberry Dudes Honey Mustard. 12 oz, plastic ringneck bottle.	Farm & Food Madison Tn	Honey, Dijon mustard, Mayonnaise, Elderberry Vinegar, Sugar, Garlic powder, cayenne pepper.		All ingredients are mixed and then placed into the 12 oz ringneck bottle, then the cap is shrink wrapped. This will produce about 391 bottles

** Food companies are required to declare eight foods as major allergens in their product according to FALCPA law. Please indicate if your product contains milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybean. Additionally, please declare if your product is produced in a facility that works with any of these allergens. Please make sure you review your ingredients carefully, if your ingredients have allergen warnings those will be carried to your final product.*

*** For the last column (description of the production), you could use bullet points to explain your procedure. Please complete this form carefully and accurately.*

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Sip & Salad Elderberry Vinegar. 12oz plastic ringneck.	Farm & Food Madison Tn	Water, honey, apple cider vinegar, vinegar, elderberries.	None	Everything is placed in a boiler and boiled then it is cooled and bottled along with shrink wrap around the lid. About 391 bottles

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Teresa Kurowski (The Elderberry Lady Of Tn) 11-5-2022

_____ *Teresa Kurowski*
 (Legal Name) (Company) (Signature) (Date)

Product Name, container material, net weight of the product, serving size per container.	Current Location of Manufacturing	Complete List of Ingredients	Allergens in the Product and production facility*	Description of Production** (Please include how many products are prepared per batch using the formulations/recipe you provide here)
Elderberry Syrup 12 OZ. Plastic ringneck	Farm & Food Madison Tn is our co-packer	Water, honey, Wildcrafted elderberries, Ceylon cinnamon sticks, fresh Ginger root, orange juice, Lemon juice,	None known of	About 391 bottles Recipe: We place all ingredients into a pressure type cooker and let boil, after a good boil and then we let it cool and place in ringneck bottles. After all the syrup is in bottles and capped we shrink wrap around the lid.