

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-023**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend Food Code – Clarification on allowable sanitizers in 4-501.114

**Issue you would like the Conference to consider:**

Section 4-501.114 of the FDA Food Code places constraints on certain variables that may impact efficacy of chemical sanitizers. Specifically, this section addresses water temperature, pH, concentration, and water hardness as it relates to efficacy of chemical sanitizers formulated with chlorine, iodine, and quaternary ammonium compounds. This section is often interpreted in such a manner as requiring all food contact sanitizers to be formulated with only one of these three active ingredients. This misinterpretation is a potential barrier to adoption of chemical sanitizers formulated with alternative active ingredients (i.e., actives other than chlorine, iodine, or quaternary ammonium compounds). Additional clarity is needed in this section in order to not inadvertently restrict innovative formulation in the area of chemical food contact sanitizers.

**Public Health Significance:**

Next generation chemical sanitizers are increasingly being formulated with active ingredients other than chlorine, iodine, or quaternary ammonium compounds. These innovative formulations have the potential to improve public health by offering broader spectrum kill claims and faster kill times for many organisms of public health significance in food settings. However, the benefits of these alternative active ingredients cannot be realized if unintended barriers to their adoption are in place. Adding clarification to section 4-501.114 will effectively lift restrictions on the innovation process in the field of chemical food contact surface sanitizers.

**Recommended Solution: The Conference recommends...:**

1. that a letter be sent to FDA requesting that Section 4-501.114 of the most current edition of the Food Code be amended as follows (added language underlined and italicized):

4-501.114 (E) If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be approved by the EPA for use as a food contact surface sanitizer, and it shall be applied in accordance with the EPA-registered label use instructions;<sup>p</sup>

1. that a letter be sent to FDA requesting that Section 4-501.114 of Annex 3 - Public Health Reasons/Administrative Guidelines be amended as follows (added language underlined and italicized):

With respect to chemical sanitization, section 4-501.114 addresses the proper use conditions for the sanitizing solution, i.e., chemical concentration range, pH, and temperature minimum levels and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these parameters are not as specified in the Code or on the EPA-registered label, then this provision is violated. *This section is not intended to limit formulation of food contact sanitizers to only chlorine, iodine, or quaternary ammonium compounds. Alternative active ingredients (e.g., ethanol, hydrogen peroxide, lactic acid, peroxyacetic acid, etc.) are permitted as long as they are listed in 40 CFR 180.940 and are approved by EPA as food contact sanitizers.*

**Submitter Information 1:**

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**Supporting Attachments:**

- "CFP Letter of Support"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

# CUYAHOGA COUNTY BOARD OF HEALTH

YOUR TRUSTED SOURCE FOR PUBLIC HEALTH INFORMATION

December 6, 2019

Chip Manuel PhD  
GOJO Industries  
One Gojo Plaza, Suite 500  
Akron, OH 44311

Dear Dr. Manuel,

Thank you for sharing your time and information regarding the Purell Food Service Surface Sanitizer. As we discussed, there are several inherent barriers to sanitarians in Ohio being able to properly understand and apply the Ohio Uniform Food Code relative to alternative and innovative food contact sanitizers, not the least of which is the language contained within the code.

When speaking with my colleagues around the state, we agree that based on our training and interpretation of the food code, first as new sanitarians and continuing through today, the trio of chlorine, iodine and quaternary ammonia sanitizers are the default choices for operators and inspectors due to their placement in the language. Over time, they have become the most commonly recognized and suggested products. With their specific concentrations being defined in the food code, it also makes it easier for sanitarians to understand and explain how to use these products.

However, the Ohio Uniform Food Code also states that any EPA-approved sanitizer that is food grade can be used on tables, utensils and all other food contact surfaces according to its label. Thus, when our agency's sanitarians see your PFSS product, we know it is approved for use. My concern is that without prior awareness and knowledge of such products and without a clearly-defined explanation of alternative active ingredients within the food code language, these products may be challenged and disapproved for use by many sanitarians, particularly those lacking extensive experience.

My suggestion for sustained clarity on this issue would be to make revisions to the FDA Model Food Code that would specifically state that chlorine, iodine and quaternary ammonia are not the only approved products. Given current conditions, it will certainly take time for new sanitarians and their trainers to understand and adopt innovative options.

Since your products are pre-mixed and ready for use, we would not require our food operators to use a kit to test their concentrations. We would suggest that sanitarians have a test kit when inspecting in case they are worried that an operator is improperly diluting the product.

Thank you for your efforts to bring increased awareness and efficiency to food service sanitization. Please don't hesitate to contact me for additional information.

Best regards,

Suzanne Hrusch MPH, RS  
Program Manager, Food Protection Unit  
Cuyahoga County Board of Health