

**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.*

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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.*