Council III Sanitizer committee update:

The committee roster is below. There has been difficulty getting participation from the EPA so the committee will prepare some recommendations and work through Morrie Potter at the FDA to help us take those recommendations to the EPA. There has been one committee conference call in November 2006 and a second is scheduled for Monday March 19, 2007. There is a draft document that has been prepared that contains the issues that have been identified with the food code as they pertain to sanitizers as well as some possible actions. This draft will be further discussed on the March 19th call. The draft document is also below. Additional calls will be scheduled during the March 19th call.

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<table>
<tr><th>Food Code Reference</th><th>Specific Food Code 2005 Citation Language (verbatim)</th><th>Potential Issue</th><th>Recommended solution for maximum public health benefit</th></tr>
<tr><td>4-501.114
Manual and Mechanical Warewashing Equipment, Chemical Sanitation – Temperature, pH, Concentration, and Hardness</td><td>A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at exposure times specified under 4-403.11(C) shall meet the criteria specified under 7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-approved manufacturer's label use instructions, and shall be used as follows:</td><td>All sanitizer formulations must be "registered" with EPA for regulatory compliance; technically they are not "approved". Each specific label is registered, not just the manufacturer or the active ingredient. Clarification of wording is needed.</td><td>Change wording from
"the EPA-approved manufacturer's label use instructions"
to
"the EPA-registered label use instructions"</td></tr>
<tr><td>4-501.114 (A)</td><td>A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart;<table><tr><th>Minimum Concentration</th><th colspan="2">Minimum Temperature</th></tr><tr><th>MG/L</th><th>pH 10 or less °C (°F)</th><th>pH 8 or less °C (°F)</th></tr><tr><td>25</td><td>49 (120)</td><td>49 (120)</td></tr><tr><td>50</td><td>38 (100)</td><td>24 (75)</td></tr><tr><td>100</td><td>13 (55)</td><td>13 (55)</td></tr></table></td><td>EPA product registration of chlorine is conducted under specific conditions, i.e. 20°C (68°F) for the test method's specified time. There is no provision on EPA labels for altering the concentration of chlorine based on pH or temperature of use.
However, it is established scientifically that the antimicrobial properties of chlorine are altered by the temperature and pH of application, which is consistent with the tabulated data.
An important application for allowing different levels of chlorine based on temperature and pH is low temperature dish machines. NSF certification requires that the manufacturer of these machines verify the operating conditions required to achieve a sanitized dish through a combination of temperature, exposure time, and effective chemical concentration. With increased emphasis on reduced energy consumption, low temperature dish machines are being considered by a significant number of food service operations</td><td>Sanitary operation of dish machines is essential to protect public health. These machines have operated safely for many years following the guidance in the table. Data generated to establish the NSF certification standard validated the science behind these applications. Since chlorine concentrations indicated in the table are lower than those already allowed for use at 20°C, environmental considerations for this application would be lower than if higher concentrations of chlorine were used.
• Recommendation: Discuss with EPA on drafting language to accept these use levels based on 1) initial data generated for validation, 2) history of safe use, and 3) lower concentrations than those allowed in other applications.
• NEED – Efficacy data from FDA or NSF to support discussion</td></tr>
<tr><td>4-501.114 (B)</td><td>An iodine solution shall have a:
(1) Minimum temperature of 24°C (75°F),
(2) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, and
(3) Concentration between 12.5 mg/L and 25 mg/L</td><td>Iodophor tests are run at 20°C (68°F), therefore the minimum temperature could be lowered.</td><td>Change 24°C (75°F) to 20°C (68°F).</td></tr>
</table>

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Potential Issue	Recommended solution for maximum public health benefit
4-501.114 (C)	A quaternary ammonium compound solution shall: (1) Have a minimum temperature of 24°C (75°F), (2) Have a concentration as specified under 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, and (3) Be used only in water with 500mg/L hardness or less or in water having a hardness no greater than specified by the manufacturer's label;	No inconsistencies are noted between Food Code and EPA requirements.	NA
4-501.114 (D)	If another solution of a chemical specified under (A)-(C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITATION and the use of the solution shall be APPROVED; or	Sanitizers must be registered with EPA for their specific use and technically must be used per label instructions. The registration process must follow specific protocols found acceptable by EPA and are conducted by the registrant. This provision provides flexibility to use other concentrations, potentially in conjunction with other treatments, as long as it is validated to be effective by the "permit holder", i.e. the legal entity operating the establishment. This is not consistent with EPA regulations, however may be beneficial to protecting public health.	As long as the level used is below that required on the EPA registered label, and data are provided by the user to demonstrate effectiveness under the conditions of use, this provision should be acceptable to protect public health.
4-501.114 (E)	If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer's use directions included in the labeling.	Sanitizers must be registered with EPA for compliance.	Insert the following "…manufacturer's EPA registered use directions included in the labeling."

Reference for 4-501.114

- Miller, M.P. Principle Investigator, 1984. Relationship of factors affecting bactericidal effectiveness of chlorine sanitizing solutions. Final report. National Sanitation Foundation, Ann Arbor, MI subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.
- Miller, M.P. Principle Investigator, 1985. Relationship of factors affecting bactericidal effectiveness of chlorine sanitizing solutions. Addendum to Final report. National Sanitation Foundation, Ann Arbor, MI subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.
- National Sanitation Foundation, Ann Arbor, MI November 1990. Report on the Bacterial effectiveness of a chlorine sanitizing solution at contact times of less than 10 seconds. Purchase Order #FDA 665531-00-90-RB.

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Potential Issue	Recommended solution for maximum public health benefit
4-703.11 Sanitation of Equipment and Utensils - Hot Water and Chemical	After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:		
4-703.11(A)	Hot water manual…	Not relevant	
4-703.11(B)	Hot water mechanical…	Not relevant	
4-703.11(C)	Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 4-501.114 by providing: (1) Except as specified under Subparagraph (C)(2) of this section, an exposure time of at least 10 seconds for a chlorine solution specified under 4-501.114(A) (2) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F), (3) An exposure time of at least 30 seconds for other chemical SANITIZING solutions, or (4) An exposure time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields SANITIZATION as defined in Subparagraph 1-201.10(B).	EPA registered labels usually specify a 1 minute contact time for sanitizing surfaces. This section provides for lower contact times, which may conflict with the registered label. As discussed in section 4-501.114, the pH and temperature provisions cited there will enhance effectiveness of the chemical and data substantiate use of a shorter time. Paragraph (4) has the same issues discussed in 4-501.114 (D)	Data to validate efficacy of the times in Subparagraphs (1) and (2) exist (Miller 1984, Miller 1985, NSF, 1990) and should be allowed. These exposure times are used for low temperature dish machine applications and are likely used in certain manual operations. Because of the generic nature of Subparagraph (3), the following modification is recommended for EPA compliance. “An exposure time per the EPA-registered label for other chemical SANITIZING solutions, or” Subparagraph (C)(4) should remain the same to allow for other validated applications as discussed in 4-501.114 (D).
7-204.11 Sanitizers, Criteria	Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).	Food Code specifically addresses chlorine, iodine, and quat while numerous other antimicrobials are listed in 40 CFR 180.940	Continue to use this as maximum allowable levels for approved sanitizers.

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Potential Issue	Recommended solution for maximum public health benefit
Annex 3 - Public Health Reasons/ Administrative Guidelines 4-501.14 Warewashing Equipment, Cleaning Frequency	With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Coordination Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day. With respect to chemical sanitization, section 4-501.114 addresses the proper make-up for the sanitizing solution, i.e., chemical concentration, pH, and temperature at the required minimum levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these minimums (maximum hardness) are not as specified, then this provision is violated. By contrast, paragraph 4-703.11(C) addresses exposure time in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met. Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.194. If the chemical used is not thus listed, this section is violated. The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the “Limits” provided for that product under its 40 CFR 180.940 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for “food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils,” each listing adding a Limit that states, ”When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound.” If a sanitarian determined that a solution of any of these quats was 600 ppm, section 7-204.11 would be violated. To summarize, a too weak sanitizing solution would be a violation of section 4-501.114. A too strong solution would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use of chemical sanitizers.	With the exception of the second paragraph of Annex 3 section 4-501.14, all of the other wording repeats wording from Annex 3 section 4-501.114. This seems to be an error because 4-501.14 addresses frequency of cleaning, with no specific mention of sanitizers, whereas 4-501.114 specifically addresses sanitizers. Inclusion of the discussion of EPA in this section therefore creates redundancy and potential confusion.	Retain the second paragraph in section 4-501.14 of Annex 3 (cited below) and delete all other wording. If other paragraphs are retained, make them consistent with wording recommended for Annex 3, section 4-501.114. Recommended wording for Annex 3, section 4-501.14: “During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.”

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Potential Issue	Recommended solution for maximum public health benefit
Annex 3 Public Health Reasons/ Administrative Guidelines 4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitation – Temperature, pH, Concentration, and Hardness	With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Coordination Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 40 CFR 180.940 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code. With respect to chemical sanitization, section 4-501.114 addresses the proper make-up for the sanitizing solution, i.e., chemical concentration, pH, and temperature at the required maximum [should state "minimum"] levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these minimums (maximum hardness) are not as specified, then this provision is violated. By contrast, paragraph 4-703.11(C) addresses exposure time in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met. Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940. If the chemical used is not thus listed, this section is violated. The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the "Limits" provided for that product under its 40 CFR 180.940 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 40 CFR 180.940(a) lists several quaternary ammonium	With the shift in regulatory responsibility, transfer of certain sanitizer provisions in the Food Code did not occur and has lead to confusion. The Food Code covers information relevant to application of sanitizers in food service operations that were not included in 21 CFR 178.1010. Specifically, the tables cited in 4-501.114 of the Food Code, and exposure times cited in 4-703.11(C). Some products (e.g. low temperature dish machine sanitizers) comply with NSF certification criteria, and no EPA protocol exists for registration of such products. EPA has approved quaternary ammonium compounds for some of these uses that are above 200 ppm. Using the example regarding 200 ppm is not consistent with approved products.	Proceed per 4-501.114 discussion above. Change language in the second paragraph as indicated. "The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. ~~All Sanitizers approved for use under 40 CFR 180.940 must be used under water conditions stated on the label to ensure efficacy.~~ Provisions of 4-501.114 have been validated to provide equivalent effectiveness at lower concentrations when used in conjunction with pH and temperature adjustment. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code." Correct typo in the third paragraph– • "maximum" should be "minimum" when referring to concentration and temperature to be consistent with the intent of 4-501.114. Change language of the second to last paragraph as follows: "The second consideration under this section is whether the product, if approved and listed, is being used in accordance with its EPA registration ~~the "Limits" provided for that produce under its 40 CFR 180.940 listing~~. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in

	compounds as approved for “food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils,” each listing adding a Limit that states, ”When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound.” If a sanitarian determined that a solution of any of these quats was 600 ppm, section 7-204.11 would be violated. To summarize, a too weak sanitizing solution would be a violation of section 4-501.114. A too strong solution would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use of chemical sanitizers.		this country. Labels on products state the use limits for specific applications. Concentrations in use should not exceed the limits stated on the EPA registered label. ~~For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for “food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils,” each listing adding a Limit that states, ”When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound.~~ If a sanitarian determined that a solution of any of these quats ~~was 600 ppm~~ exceeded the labeled concentration, section 7-204.11 would be violated.”