Food Code recommendations for on-site generation of antimicrobials
(Table 1 extracted from the 2008-2010 CFP Sanitizer Committee Final Report)

Table 1 Recommended Food Code modification to address on-site generation of antimicrobial pesticides
[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
4-204.124 On-Site Devices for Generation of Sanitizing Solutions new section	None	Chapter 4 of the Food Code addresses equipment for use in food establishments, and Part 4-2 specifically addresses the design and construction of such equipment. This section covers the equipment itself, NOT the solutions that the devices generate. It is important to address the equipment in the Food Code because FIFRA regulations require registration of the device manufacturer and not the resulting solution. The solutions are covered in subsequent sections.	4-204.124 On-Site Devices for Generation of Sanitizing Solutions Devices for generation of sanitizing solutions shall meet the characteristics specified under §4-202.11 and (A) Devices for generating pesticides must comply with regulations as established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. (B) Devices for generating pesticides shall display the manufacturing establishment's registration number.
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness (F) new paragraph	A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows [P]: … A-E unaltered	A sanitizer generated on-site should provide the same level of biocidal efficacy as a sanitizer manufactured in a different facility. A manufactured sanitizer must meet EPA testing and performance standards outlined in the Disinfectant – Technical Science Section DIS-TSS 4. Currently, no similar regulatory standard for solutions generated and used on-site exists. Pesticide devices and the sanitizers they produce for application on-site are exempt from registration requirements according to 40 CFR 152.500. At this point the EPA has not mandated registration of solutions produced by a pesticide device unless distributed or sold, but EPA does require that statements of performance, safety and efficacy related to the solution be true. ¶4-501.114 (D) refers to the use of chlorine, quats, or iodine based sanitizers at conditions and concentrations outside those specified in ¶¶ 4-501.114 (A)-(C). ¶4-501.114 (D) permits the use of those biocides if the permit holder demonstrates efficacy. ¶4-501.114 (E) allows the use of biocides other than chlorine, quats, or iodine, when used according to EPA-registered use instructions, which requires demonstration of efficacy by the supplier, which is accomplished by the EPA-registered label. This paragraph is not applicable to solutions generated on-site because there is no EPA-registered label, no efficacy standard and no regulatory oversight for such solutions that are generated and used on-site. New ¶4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and defines an efficacy standard that those solutions can be validated against. Guidance to the field regulatory personnel on how to verify that efficacy is proven is provided in Annex 3 for §4-501.114 (suggested language is below).	"A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows [P]: … (F) Any chemical substance produced and used on-site as a food contact surface SANITIZING solution shall have the concentration, temperature, pH and other conditions necessary to meet the definition of SANITIZATION in §1-201.10.

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Annex 3 Public Health Reasons/ Administrative Guidelines Chemicals 4-501.114	New paragraphs within that section	The inclusion of ¶4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and provides an efficacy standard for those solutions. The field regulatory personnel may require guidance on how to verify that efficacy is met, which is addressed in the added paragraphs.	See below underlined section below.

Annex 3.
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Correction 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 Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. Provisions for pH, temperature, and water hardness in section 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels. Therefore, it is critical to sanitization that the sanitizers are used consistently with the EPA-registered label, and if pH, temperature, and water hardness (for quats) are not included on the label, that the solutions meet the standards required in the Code.

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.

By contrast, paragraph 4-703.11(C) addresses contact time in seconds. For chemical sanitization, this paragraph is only violated when the specified contact time is not met.

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940.

EPA sanitizer registration assesses compliance with 40 CFR 180.940; therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for further compliance verification. If a sanitarian determined that a solution exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on the EPA-registered label, section 7-204.11 would be violated.

A variety of sanitizers can be generated on-site, including chlorine, hypochlorous acid (generated by processes known as electrolyzed water, electro chemically activated water, electro activated water, etc.), chlorine dioxide, ozone, and others. EPA does not require the registration of pesticidal devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this standard include, but are not limited to:

- The name, brand, or trademark under which the product is sold
- An ingredient statement
- Statements concerning effectiveness of the product
- Hazard and precautionary statements for human and domestic animals
- Environmental and exposure hazards
- The directions for use

Because there is no EPA registration of solutions generated and used on-site, either the equipment manufacturer or the user of the equipment must generate data to validate the efficacy of the solution the device produces as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site. Section 4-703.11 requires that the conditions of use yields SANITIZATION as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.

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	EPA Disinfectant – Technical Science Section (DIS-TSS) 4 describes efficacy data requirements for sanitizing rinses for previously cleaned food-contact surfaces http://www.epa.gov/oppad001/dis_tss_docs/dis-04.htm. Chlorine equivalent testing is used for halide-based biocides (chlorine bearing chemicals, iodophors, and mixed halides) and a minimum of 99.999% reduction of *E. coli* and *S. aureus* for non-chlorine biocides. These procedures are required for EPA-registered sanitizers (e.g., bottled chlorine, iodine, quats, etc.), but modification is needed for on-site generated sanitizers. For example, the procedures specify that 3 different batches are to be tested, one of which must be 60 days old. A 60 day sample would not be relevant for on-site generated sanitizers because they should be used shortly after generation. Validation testing for on-site generated product should include a time element, because efficacy can reduce with time. Testing should include all factors that could impact the efficacy of the pesticide solution including water hardness, pH and temperature. The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the test. This testing is best performed under Good Laboratory Practices. Some technologies generate chemicals that are addressed in the Code, such as chlorine or hypochlorous acid. Verifying performance of these chlorine-based solutions can be accomplished by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with paragraph 4-501.114 (A) using test methods and equipment that is currently used. However, some on-site generators produce chemicals that are not listed as sanitizers in the Code (e.g. ozone, chlorine dioxide, hydrogen peroxide, etc.). The manufacturer should provide methods (e.g., test strips, kits, etc.) to verify that the equipment continues to generate the solution at the same concentration on-site. Some solutions, such as ozone, chlorine dioxide, and hypochlorous acid, may lose concentration more quickly than other solutions. Therefore, it is necessary to verify concentration on an on-going basis, and to comply with section 4-501.116. To summarize, a sanitizing solution that is too weak would be a violation of section 4-501.114. A solution that is too strong 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 chemical sanitizers.		
7-204.11 Sanitizer, 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). [P]	§7-204.11 addresses the toxicity of solutions used as sanitizers and requires them to comply with the EPA tolerance exemptions outlined in 40 CFR 180.940. Solutions generated on-site should comply with the same tolerance exemptions. The one exception to this is ozone, which is not addressed in 40 CFR 180.940. However, ozone is approved as a secondary food additive in 21 CFR 173.368 so ozone solutions generated on-site comply with the intent of that regulation. Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns. Verification of compliance with 40 CFR 180.940 also requires some clarification. Annex 3 §7-204.11 should address this (suggested language is below).	Chemical SANITIZERS, including those generated on-site, and other chemical antimicrobials applied to FOOD-CONTACT SURFACEs shall: (A) 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) [P]", or (B) be listed in 40 CFR 180.2020 Pesticide chemicals not requiring a tolerance or an exemption from a tolerance - Non-food determinations.

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Annex 3 – Public Health Reasons/ Administrative Guidelines Chemicals 7-204.11 Sanitizers, Criteria.	7-204.11 Sanitizers, Criteria. See explanation in § 4-501.114 Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.	Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples of these technologies are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns and Annex 3 § 7-204.11 should address them.	7-204.11 Sanitizers, Criteria. See explanation in § 4-501.114 Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe. Some SANITIZERS produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. OSHA limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility. The permit holder using a pesticide device is responsible for being in compliance with 40 CFR 180.940. Because no process for regulatory review of the output of a pesticide device exists, no standard method for checking compliance exists. As such, a potential user of a pesticide device needs to look elsewhere for evidence of compliance. This may include a statement from the device manufacturer, an analysis of the MSDS ingredient statement or a third party chemical analysis of the device output.

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7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.	(A) Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. P (B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.	§7-204.12 also addresses chemicals used for washing fruits and vegetables and requires them to comply with 21 CFR 173.315. Solutions generated on-site should comply with the same CFR.	(A) Chemicals including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. P (B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.