COMMITTEE NAME: 2008-10 Sanitizer Committee

COUNCIL (I, II, III): III

DATE OF REPORT: 22 December 2009

SUBMITTED BY: Katherine MJ Swanson & Tressa Madden, Co-Chairs

COMMITTEE CHARGE(S): to work with the FDA, EPA and other stakeholders to develop appropriate language for the Food Code addressing on-site generation of pesticides in food establishments and report back to the 2010 CFP Council III.

The term “pesticides” in the context of this charge was considered by the committee to mean sanitizers and potentially other antimicrobial solutions, but not rodenticides or agricultural pesticides. This is consistent with the name of the committee; i.e., the “Sanitizer” Committee.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Specific Activities
Committee completed the charge through 12 conference calls, a few sub-committee conference calls, and email comments on working drafts. See Appendix 1 for dates and activity on conference calls. The work of the Committee focused on three (3) specific activities:

1. Describing the current federal regulatory requirements for on-site generators of antimicrobial pesticides
2. Addressing unresolved questions related to on-site generators of antimicrobial pesticides
3. Developing specific recommendations for language in the Food Code for on-site generation of antimicrobial solutions.

This report addresses each of these activities.

Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments

Background

- The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 was enacted to regulate the marketing of pesticides and devices, and for other purposes.
- By law, the Environmental Protection Agency (EPA) is authorized to register a pesticide for sale and distribution in the United States only if it will not cause unreasonable adverse effects on human health or the environment when used according to its label.
- FIFRA provides EPA with the authority to oversee the registration, distribution, sale, and use of pesticides. FIFRA applies to all types of pesticides (unless exempt), including but not limited to antimicrobials. The antimicrobial class of pesticides includes disinfectants, sanitizers and other substances that are intended to control microorganisms in or on various surfaces or media. FIFRA requires sellers, distributors and users of registered pesticide products to follow the labeling directions on each product explicitly.
- Under FIFRA, no one may sell or distribute or use a pesticide or an article containing a pesticide, including but not limited to an antimicrobial pesticide, unless it is registered by EPA, or unless it is exempted by the regulations.
On-site Generator Status

- On-site generators of hard surface sanitizers/disinfectants, such as chlorine dioxide, ozone, hypochlorous acid (HOCl, generated by processes known as electrolyzed water, electrochemically activated water, electro activated water, etc.), are currently classified by EPA as devices.
- EPA does not currently require the registration of pesticidal devices; however, devices are not exempt from other pesticide requirements under FIFRA particularly with regards to labeling as defined in the Code of Federal Regulations (CFR) 40 CFR 156.10.

FIFRA Requirements

- All on-site generating devices are subject to a number of FIFRA’s provisions, including labeling standards and production in registered establishments.
- On-site generators are subject to EPA device labeling requirements. No person may sell or distribute a pesticide device that is misbranded.
- The requirements for device labels 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 following:
  - The name, brand, or trademark under which the product is sold
  - An ingredient statement
  - Statements concerning effectiveness of product
  - Hazard and precautionary statements for human and domestic animal hazards
  - Environmental and exposure hazards
  - The directions for use
- This provision of FIFRA is critical because it deals with statements of composition, antimicrobial effectiveness and safety of a pesticide or device.
  - Because there has been no requirement for device registration, what we see in the marketplace tends to be self-certification of the performance, safety and efficacy of pesticide devices.
  - Third party data is presently acceptable to demonstrate due diligence in making pesticide claims on on-site generated and applied sanitizers. A certified lab is not required, and EPA fees are not assessed for each claim made.
  - EPA expects a device manufacturer to be able to substantiate claims. A device making a sanitizer claim is expected to meet the same performance standard using the same testing methodology as that of a registered pesticide product making a sanitizer claim.
- On-site generators may also be subject to state regulation. Each state can have its own statutes and regulations concerning pesticide and pest control device registration and regulation.

2009 Food Code Recommendations

- On-site generators of antimicrobial solutions are not specifically mentioned in the Food Code under Equipment or other provisions.
- Equipment must meet the recommendations of Food Code Parts 4-1 “Materials for Construction and Repair” and 4-2 “Design and Construction”. According to § 4-205.10, equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program are deemed to comply with Parts 4-1 and 4-2 of this chapter. As an example, an NSF Certification process includes:
  - Physical evaluations of design and construction, material evaluation and performance testing (when required).
Material requirements, including specifications that all materials that have contact, or potential contact, with food must not contribute contaminants of toxicological significance to the food.

Performance testing to verify that equipment conforms to all performance requirements of the standard. Note – Many products are certified to NSF Standard 169 for Special Purpose Food Equipment and Devices. This standard includes requirements for design, construction and materials but not efficacy of microbial claims.

Equipment must meet the recommendations of § 4-402.11 “Fixed Equipment, Spacing or Sealing”.

Resolution of 2008 Questions on On-site Generators of Antimicrobial Pesticides

At the 2008 Biennial Meeting of the Conference for Food Protection, the FDA posed questions related to on-site generators of antimicrobial pesticides. The Sanitizer Committee was formed, in part, to address these questions. The following questions (in bold and italics) were posed to the committee. The Sanitizer Committee answered the questions in a general manner, rather than focusing on specific generators. This will hopefully allow for introduction of new antimicrobials in the future, as long as they meet the general requirements.

1. **Does the chemical produced comply with §7-204.11 “Sanitizers, Criteria,” which states that the sanitizer shall meet the requirements of 40 CFR §180.940?**

   - Of the on-site generated chemistries that the Committee considered (e.g., chlorine dioxide, hypochlorous acid, sodium hypochlorite, ozone), only chlorine dioxide, hypochlorous acid, hydrogen peroxide, and sodium hypochlorite are listed in 40 CFR 180.940 “Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).” Ozone is not listed in 40 CFR 180.940, but it is approved under 21 CFR 173.368 as a secondary food additive. The 2009 Food Code also includes a new approved use of ozone in §7-204.12 as follows: “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.”

   - In the opinion of the majority of the Committee based on science, it seems reasonable that ozone and other secondary food additives should be allowed for sanitization of a food contact surface, if efficacy can be demonstrated and levels used are below those listed for secondary food additives.

   - EPA’s position is that any chemical used on a food contact surface for sanitization purposes must be listed in 40 CFR 180.940 unless data are submitted showing there is no residue. If there is no residue, EPA would likely list the ingredient in 40 CFR 180.2020. Ozone is not listed in either reference. EPA procedures exist to add other sanitizers to the list if providers chose to do so, although this may not be a rapid process.

2. **Does the unit comply with the requirements of FIFRA as implemented in 40 CFR §152.500?**

   - 40 CFR 152.500 addresses EPA requirements for pesticide devices, but no list of “approved” sanitizer generating devices currently exists. Further, the regulation does not specifically indicate whether an ozone, chlorine dioxide or electrolytic chlorine generator, as a class, falls under this regulation. Rather, the regulation specifies the requirements that a manufacturer must meet for an on-site generating device to comply with the regulation. The committee cannot determine if any or all on-site generators would meet this regulation. Compliance with the regulation falls to the specific pesticide device and the device manufacturer.
• The manufacturer of the generator should provide documentation that the device complies with 40 CFR 152.500 and the manufacturing establishment’s registration number should be on the device. Compliance with 40 CFR 152.500 goes beyond labeling of the device with an EPA establishment number. The device must also comply in regard to how it is “labeled and marketed.” Language regarding labeling and marketing for both pesticides and devices in 40 CFR 156.10 reads as follows:

“5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

“(i) A false or misleading statement concerning the composition of the product;
“(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
“(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
“(iv) A false or misleading comparison with other pesticides or devices;
“(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;”

• Other provisions related to claims as to the safety of the pesticide or its ingredients are addressed in 40 CFR 156(a)(5)(ix). For example, “including statements such as ‘safe’, ‘nonpoisonous,’ ‘noninjurious,’ ‘harmless’ or ‘nontoxic to humans and pets’ with or without such a qualifying phrase as ‘when used as directed’ ” may also be considered false or misleading.

• No regulatory body oversees testing that a device is in compliance with its labeling, therefore a user of an on-site generator or an inspector must rely on the manufacturer to self affirm that the device complies with the regulation when used according to the manufacturer’s instructions. Compliance would involve validation that the output of a device is effective for its claimed uses and verification that the output of the device is within the required concentration, pH, oxidation reduction potential (ORP), or other parameters required to be effective at the point of use.

3. Are there occupational exposure concerns that make the unit unsuitable for a retail/foodservice setting?

Depending upon the on-site generator being considered, there may or may not be occupational exposure concerns for a unit. The Committee believes that addressing this question in detail is outside of the scope of the original charge; i.e., “to develop appropriate language for the Food Code addressing on-site generation of pesticides in food establishments.” Historically, the Food Code has not been a vehicle to address occupational safety issues; rather it provides guidance to address food safety issues. For example, slicers have occupational safety issues, which are not reviewed in great depth in the Food Code. Should FDA wish to address occupational safety issues, OSHA limitations such as those in 29 CFR 1910.1000 could be referenced. Manufactures should include information based on
occupational issues and include appropriate sensors, timers, or shut off devices, as appropriate, to protect workers.

4. Are there operational and user training issues, such as ability to adjust and maintain proper output concentrations that make it unsuitable for retail/foodservice?

The Committee cannot answer this question for all potential devices available now or in the future, as the level of operational and training issues will vary. In general, the equipment must be installed properly, with sufficient capacity to produce the volume of sanitizer required. This will vary by location and use requirements. Food workers must know how to use the equipment properly, how to verify that the output is at the proper concentrations, and how to maintain the equipment. This is similar to other devices that may be used in a foodservice or retail establishment.

An example of information that is provided on certain devices is the following UL 979 disclaimer for “Water Treatment Appliances”:

“This category covers water treatment equipment employing ozone generation, investigated with respect to mechanical, electric shock, and fire hazards only. Maximum ozone threshold limit recommendations are set by the American Conference of Governmental Industrial Hygienists as found in 21 CFR 801.415 “Maximum Acceptable Level of Ozone.” Compliance with the applicable regulations under conditions of normal and abnormal operation has not been investigated. The methods for controlling ozone release or the effectiveness of the water treatment have not been investigated.”

- Visible onboard indicator of in-spec operation. Many ozone generators are adjustment free. When activated, they simply turn the supply of ozonated water on or off. Detailed installation and operating instructions should be concise and appropriate for the target audience.

- Emergency shut-off is recommended.

Both ozone and chlorine dioxide generators produce a gas dissolved in water, and the level present in the water is impacted by temperature of the water and mechanical agitation. Therefore, the concentration and potential efficacy of a solution of ozone or chlorine dioxide can change depending on how the solution is used. For example, a solution containing 5 ppm active ozone or chlorine dioxide in a spray bottle may have less than 1 ppm when that solution is sprayed onto a surface. A solution of ozone or chlorine dioxide made in 35°C water will have a lower active concentration than the same solution generated in 25°C water because of the potential for off-gassing. This phenomenon impacts both the safety and efficacy of the solution. Because of the potential for diffusion of the gas out of water, the concentration of the active ingredient is most accurately verified on the surface being sanitized, rather than in the stock solution prior to application (e.g., spraying the solution on a test strip rather than dipping the strip into the solution). This is unique to a gas dissolved in water because chemical solutions are not subject to the same type of activity loss through spraying. Users need to be trained on this to ensure proper operation.

The chemistries produced by an on-site generator can be tested for microbial efficacy under the same Association of Official Analytical Chemists (AOAC) standard used by the EPA for sanitizer registration. There is need for training of inspectors and users to understand how to determine if the solution generated has antimicrobial efficacy consistent with these standards. Unlike EPA-registered sanitizers, there is no list or registration number that the user or inspector can use to make this determination.
Because pesticidal devices are exempt from registration, EPA cannot require that efficacy data be submitted and will not approve a label for these devices for the same reason. The Committee suggests that data be developed under Good Laboratory Practices (GLP) using accepted AOAC methods specific to the active species produced by the given pesticide device.

Under proper concentration, contact time, temperature and pH, these chemistries can be effective sanitizers for food contact surfaces. There is need to validate and verify that the output of one of these systems can meet the definition of sanitization defined in §1.201 of the Food Code. No standard process exists to achieve this; however, it may be possible to require manufacturers to provide information on how they demonstrated effectiveness if they market the product for the purpose of generating a sanitizing solution.

Test strips as well as colorimetric and titrimetric methods exist for ozone, chlorine dioxide and HOCl/NaOCl, therefore the concentration can be verified on-site for any of these technologies. These should be used operationally to verify that the proper concentration is used and training is needed to ensure that the test methodology is used correctly.

Environmental monitors exist for ozone and chlorine dioxide that could provide background surveillance of the environment. Currently these devices may be prohibitively expensive and thus may not be practical in a food service or retail setting. Monitoring devices may not be necessary if it can be shown that the device cannot produce an output level considered by OSHA to be hazardous.

Other operational considerations include:

- Chlorine dioxide and ozone are minimally impacted by pH and hardness.
- The efficacy of HOCl/NaOCl is impacted by pH in a manner that is consistent with pH and temperature already identified in the Food Code, but it is minimally impacted by water hardness.
- In cases of water treatment, all of these oxidizers should be dosed at a concentration that overcomes the organic demand, leaving some residual active to provide kill. It is reasonable to think the same approach could be used for hard surface sanitization.
- An additional issue exists around controlling the concentration of ozone and chlorine dioxide in variable water conditions (temperature and agitation). This should be addressed by the manufacturer’s instructions.

For the technologies considered, the potential for corrosion appears to be minimal under anticipated use conditions. For ozone and chlorine dioxide, the levels of active ingredient that would be required to achieve sanitization are in the single to tens of ppm levels. Further, ozone and chlorine dioxide disperse into the air as a water solution dries on a surface, making corrosion potential at typical use dilution levels minimal. However, in a closed space, chlorine dioxide has been known to cause corrosion on the top of a stainless steel container. With HOCl/NaOCl there is a breadth of historical experience of compatibility over the slightly alkaline pH ranges typically seen with commercial chlorine bleach (pH 8-10 in use dilution). An on-site generated solution with an equivalent pH and available chlorine content would likely have a similar performance profile. Acidic solutions of HOCl/NaOCl in the pH range of 2-4 could be more problematic over extended periods of time because of the high potential for chloride ion pitting on stainless steel under low pH high
chloride conditions. Any surface that is incompatible with bleach would also be incompatible with a generated solution of HOCl/NaOCl. The manufacturer’s information should provide guidance on material compatibility for the product to assist with proper training and operation.

5. **Has the device been accepted for use in other non-retail applications? By whom?**

As previously mentioned, on-site generation of ozone, chlorine dioxide and HOCl/NaOCl are being used industrially for water treatment, bleaching, waste water recovery, and poultry washing. Ozone, chlorine dioxide and HOCl/NaOCl have also been used for laundry applications. Additionally, on-site generated HOCl/NaOCl and chlorine dioxide are used as high level disinfectants to decontaminate medical devices such as heat flexible endoscopes. On-site generators are used in dental applications to decontaminate dental unit waterlines, sanitize/disinfect dental office surfaces and as endodontic cleaners. HOCl/NaOCl on-site generators are used to treat acute and chronic wounds. On-site generators of chlorine dioxide and HOCl/NaOCl are used in agricultural applications to generate disinfecting agents. Furthermore, HOCl/NaOCl on-site generators have been approved by FDA as high level disinfectants, as a wound care irrigants and also as endodontic cleaners. There may be other applications.

6. **Does the manufacturer, the device and/or the sanitizer produced need to be EPA registered?**

There are FIFRA requirements that apply to the manufacturers of pesticidal devices. Also, the need for sanitizer registration depends on the nature of the sanitizer produced, by whom it is applied and whether there is intent to package/sell/distribute it.

Refer to the previous section on ‘Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments.’

**Recommended Food Code Language for On-site Generation of Antimicrobial Solutions**

Based on the Committee’s deliberations and the specific charge to identify language related to on-site generation of antimicrobial pesticides, the Committee identified several sections of the Food Code where on-site generators should be addressed. These are discussed in Table 1, which includes rationale for the change and specific language recommendations.

**Specific Recommendations:**

1. **Consider the recommended language in Table 1, including:**
   a. Adding §4-204.124 to address equipment requirements for on-site generators
   b. Adding ¶4-501.114 (F) to address the sanitizing solutions generated on-site
   c. Updating Annex 3 for §4-501.114 to address FIFRA requirements for on-site generators
   d. Adding ¶7-204.11 (B) to address pesticides that may not required a tolerance
   e. Updating Annex 3 for §7-204.11 to address OSHA limits for gases dissolved in solution
   f. Update §7-204.12 to address on-site generation of chemicals to wash vegetables.

2. **The Committee requests that the Sanitizer Committee be disbanded and note that the assigned charges are completed.**

**REQUESTED ACTION:**

The 2008-10 Sanitizer Committee is submitting two issues to the 2010 Biennial Meeting of the Conference for Food Protection:

1. **Report – Sanitizer Committee**
2. **On-Site Generation of Antimicrobial Pesticides**
The following attachments are also submitted:

1. ‘2008-10 Sanitizer Committee Final Report’
2. ‘2008-10 Sanitizer Committee Roster’
3. ‘Food Code recommendations for on-site generation of antimicrobials’ (extracted from Committee Report)

COMMITTEE MEMBER ROSTER
An abbreviated list of committee members follows, and a detailed list with contact information is attached. The Co-Chairs wish to thank these active committee members for their expertise and dedication to understanding this complex issue.

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<thead>
<tr>
<th>Name</th>
<th>Employer</th>
<th>City</th>
<th>State</th>
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<td>Brania, Jonathan</td>
<td>Underwriters Laboratories, Inc.</td>
<td>Research Triangle Park</td>
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<td>Brickey, Matthew</td>
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<td>Malvern</td>
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<td>Swanson, Katherine (Co-Chair)</td>
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The Sanitizer Committee thanks the Conference for Food Protection for the opportunity to explore this topic and hopes that the work of our Committee will benefit CFP and public health at large by harmonizing the language and clarifying jurisdictional authority for sanitizer use in retail and food service settings.

Respectfully submitted by,

Katherine MJ Swanson and Tressa Madden, Co-Chairs for the 2008-10 CFP Sanitizer Committee
Table 1 Recommended Food Code modification to address on-site generation of antimicrobial pesticides

<table>
<thead>
<tr>
<th>Food Code Reference</th>
<th>Food Code 2009 Citation Language (verbatim)</th>
<th>Rationale for Recommendation</th>
<th>Recommended Language</th>
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| 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. |
Food Code Reference | Food Code 2009 Citation Language (verbatim) | Rationale for Recommendation | Recommended Language
--- | --- | --- | ---
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.
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

<table>
<thead>
<tr>
<th>Food Code Reference</th>
<th>Food Code 2009 Citation Language (verbatim)</th>
<th>Rationale for Recommendation</th>
<th>Recommended Language</th>
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<tbody>
<tr>
<td>§7-204.11 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).</td>
<td>§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.</td>
<td>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) or be listed in 40 CFR 180.2020 Pesticide chemicals not requiring a tolerance or an exemption from a tolerance - Non-food determinations.</td>
<td>(B) 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).</td>
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<td>Annex 3 – Public Health Reasons/ Administrative Guidelines Chemicals 7-204.11 Sanitizers, Criteria.</td>
<td>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.</td>
<td>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.</td>
<td>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.</td>
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<td>7-204.12</td>
<td>(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.</td>
<td>§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.</td>
<td>(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.</td>
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Appendix 1. Conference Call Dates and Accomplishments

1. December 8, 2008 – Reviewed FDA questions and identified electrolyzed water, ozone, and chlorine dioxide as the primary on-site generated antimicrobials to consider. Broke into sub-groups to address technologies.

2. January 28, 2009 – A draft of the “regulatory status” of on-site generators was introduced to provide the committee with background on the regulatory framework involved with these devices. This was the starting point for the “Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments” section of this report.

3. March 6, 2009 – Chlorine dioxide was removed from the list of antimicrobials because no one was aware of commercial applications for retail and food service. Examples of labeling for on-site generated sanitizers were provided.

4. April 17, 2009 – Continued to refine the “regulatory status” draft, limited work progressed on individual technologies; group formed to identify areas of the Food Code with language to be addressed.

5. June 1, 2009 – “Regulatory status” draft discussed, but lack of quorum prevented finalization.

6. June 27, 2009 – “Regulatory status” draft finalized after moving 6 former members to “inactive” status. This allowed the committee to achieve quorum.

7. July 31, 2009 – Began review of citations in the Food Code that could be addressed related to on-site generation of sanitizers. The complexity of the issue stimulated a request to review the initial questions of FDA. Co-chairs reviewed alternative to proceed. The charge specifically directed the committee to develop language for the Food Code, but the questions deal with general terms that may or may not be relevant to Food Code language.

8. September 25, 2009 – Draft answers to FDA’s questions were provided to the committee for discussion and comment. A sub-committee was appointed to further refine the answers to FDA’s questions.

9. October 19, 2009 – The sub-committee focused on potential language for recommended changes to Food Code language rather than addressing FDA’s questions. This work addressed the specific charge to the committee, but did not address original questions posed at the 2008 CFP related to on-site generated sanitizers. A work group was formed to draft a final report that addressed:
   a. Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments (based on the “regulatory status” draft finalized June 27 by the committee),
   b. Resolution of 2008 Questions on On-site Generators of Antimicrobial Pesticides (to address FDA concerns) and
   c. Recommended Food Code Language for On-site Generation of Antimicrobial Solutions (to address the Committee charge).

10. November 12, 2009 – Draft final report discussed up to citation recommendations
