

**Conference for Food Protection  
2010 Issue Form**

**Internal Number: 005  
Issue: 2010 III-005**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

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

---

**Title:**

On-Site Generation of Antimicrobial Pesticides

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

To accomplish its charge, the 2008-10 Sanitizer Committee thoroughly reviewed three specific aspects related to on-site generation and use of sanitizers and other antimicrobials. These included 1) the current federal regulatory requirements for on-site generators of antimicrobial pesticides and 2) unresolved questions related to on-site generators of antimicrobial pesticides, and 3) specific recommendations for language in the Food Code for on-site generation of antimicrobial solutions. The Committee would like the Conference to consider its recommended language related to on-site generation and use of antimicrobials.

**Public Health Significance:**

Proper use of sanitizers is an important step to prevent cross contamination and food safety failures. On-site generation of sanitizers and other antimicrobials is not addressed in the 2009 Food Code, and the regulatory process for sanitizers generated and used on-site varies considerably from the regulatory process for manufactured products. Clarification of the Food Code requirements for on-site generated sanitizers is essential to ensure proper use of these materials and to avoid unproductive confusion for inspectors and operators.

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

that a letter be sent to the FDA recommending changes to the Food Code as detailed in the attached "Food\_Code\_Recommendations\_for\_On-site\_Generation\_of\_Antimicrobials" (extracted from Table 1 of the CFP 2008-10 Sanitizer Committee Final Report). Detailed rationales for the recommended changes are included in the table.

The recommended new language is indicated below in underline format for additions and plain text for current 2009 Food Code language:

1. Adding §4-204.124 to address equipment requirements for on-site generators

"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."

2. Adding §4-501.114 (F) to address the sanitizing solutions generated on-site

"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 <sup>P</sup>:

...

"(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."

3. Insert the following in Annex 3 for §4-501.114 to address FIFRA requirements for on-site generators, as indicated in the attachment.

"...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](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..."

4. Adding ¶7-204.11 (B) and inserting a reference to on-site generated antimicrobials to address pesticides that may not require a tolerance. The section to read as follows.

"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)<sup>P</sup>, or

(B) be listed in 40 CFR 180.2020 Pesticide Chemicals Not Requiring a Tolerance or an Exemption From Tolerance - Non-food determinations."

5. Adding the following at the end of existing Annex 3 for §7-204.11 to address OSHA limits for gases dissolved in solution.

"...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 throughout 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."

6. Update ¶7-204.12 (A) to address on-site generation of chemicals to wash vegetables.  
"(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"

**Submitter Information:**

Name: Katherine M.J. Swanson, Co-Chair  
Organization: Sanitizer Committee  
Address: Ecolab Inc.655 Lone Oak Drive  
City/State/Zip: Eagan, MN 55121  
Telephone: 651-795-5943 Fax: 651-204-7516  
E-mail: katie.swanson@ecolab.com

**Attachments:**

- "Food\_Code\_Recommendations\_for\_On-site\_Generation\_of\_Antimicrobials"

*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.*