



Safety Innovations

Making Chemical Sanitizing Solutions On-Site

FOOD PROTECTION CONNECTION



INNOVATIONS
FEATURE

FDA REGULATIONS PERTAINING TO MAKING YOUR OWN SANITIZERS ON-SITE

Chemical sanitizers are included among poisonous or toxic materials because they may be harmful or even deadly 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 residue remains. The CFR lists sanitizers and the concentrations considered safe for use with food contact surfaces. The FDA Food Code goes into great detail regarding use of sanitizers within a foodservice operation. But what if you want to

make your own sanitizer on-site and not buy the chemical from a distributor?

A variety of hard food contact surface sanitizers such as chlorine dioxide (ClO₂), hypochlorous acid (HOCl), and sodium hypochlorite (NaOCl) can be produced by on-site generating devices by technologies known as:

- Electrolyzed water
- Electro-chemically activated water
- Electro activated water



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WHAT IS ELECTROLYZED WATER?

Electrolyzed water is a good sanitization method because it has antimicrobial properties; is not corrosive to skin, mucous membranes, or organic material; is safe to handle; and has little adverse effect on the environment. Electrolyzed water shows effectiveness against a wide range of microorganisms. It can be produced easily using common salt and an apparatus connected to a power source. Because the size of the machine is quite small, electrolyzed water can be manufactured on-site. The initial capital expenditure to purchase a device is high; however, once installed, the cost to produce sanitizer is low. Electrolyzed water can be corrosive to certain metal surfaces.

The FDA Retail Food Code addresses the efficacy and use of these on-site generated solutions and requires that the conditions of use yields sanitization as defined, i.e., a 5 log (99.999 percent) reduction.

Believe it or not, a device used to generate hard food contact surface sanitizers on-site is considered a pesticide device. The Environmental Protection Agency (EPA) defines a

device in 40 CFR 152.500, Requirements for Devices, as “(a) A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals), but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.”

The EPA does not require the registration of pesticide devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment’s registration number. Additionally, device label requirements are established by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as well as the Code of Federal Regulations (40 CFR 152.500 Requirements for Devices and 156.10 Labeling Requirements). No statement that is false or misleading can appear in a device’s labeling. Statements that are subject to this regulation include, but are not restricted to:

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

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.

Any on-site produced sanitizer that is intended to be used to wash or peel raw, whole fruits and vegetables or used in the treatment, storage, and processing of fruits and vegetables shall be an approved food additive and generally recognized as safe (GRAS) under the Code of Federal Regulations. Users with this purpose should have documentation from the device manufacturer of these requirements.

As with any equipment, to ensure that these generators continue making the sanitizer chemical in

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the form and concentration that is required, maintaining and cleaning the device is necessary. All manufacturer's instructions should be followed.

VERIFYING EFFICACY AND SAFETY

Verifying the adequacy of your standard sanitizing agents can be achieved on an on-going basis by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with the Food Code using acceptable test methods (test strips) and equipment. Just as with standard sanitizers, the manufacturer of the chemical produced on-site should provide methods (e.g., test strips, kits, etc.) to verify that the equipment consistently generates a solution on-site at the necessary concentration to achieve sanitization.

Chemical sanitizers used in your facility typically require EPA registration and approval; however, this is not the case with on-site generated sanitizers. Because the EPA does not require registration of solutions generated and used on-site, the user of the equipment should look to the device manufacturer for:

- Data to validate the effectiveness of the solution produced by the device
- Conditions for use of the solution such as
 - > Concentration
 - > Temperature
 - > Contact Time
 - > pH
 - > Other applicable factors

This data should be available on-site in the food establishment.

The Food & Drug Administration (FDA) Model Food Code addresses whether or not the chemical agent being applied (chlorine dioxide (ClO₂), hypochlorous acid (HOCl), sodium hypochlorite (NaOCl)) as a sanitizer is approved and listed for that use under "Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations: food contact sanitizing solutions" (40 CFR 180.940) or "Non-food determinations" (40 CFR 180.2020).

Since there is no EPA registration of solutions generated and used on-site, *the user of the equipment should look to the equipment manufacturer for data to validate the*



CHEMICAL SANITIZERS used in your facility typically require EPA registration and approval; however, this is not the case with on-site generated sanitizers.

effectiveness of the solution that is produced by the device, as well as the conditions for use of the solution.

Any data used to validate the effectiveness of on-site generated sanitizer solutions should include validation testing by the manufacturer that contains all factors that could impact the efficacy of the sanitizer solution, including water hardness, pH, temperature, and a time element because efficacy can reduce with time. *The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the validation standards of a 5-log reduction.* The maximum concentration of the applied chemical should also be documented, since above that level the chemical could be toxic. The end-user of the chemical must know the minimum and maximum concentrations (usually in parts per million, ppm).

Some sanitizers produced by on-site generators are based on gases dissolved in solution, such as ozone and chlorine dioxide. These may present toxicology issues if the gases can come out of solution and into the air at

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high concentrations. Occupational Safety and Health Administration (OSHA) limits on gases like ozone and chlorine dioxide are outlined in the CFRs under “Air Contaminants.” 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 user 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 foodservice facility.*

As with any sanitizer you may purchase from a supplier, if a facility is going to invest in an on-site generated sanitizer device the person in charge and the foodservice employees must know the proper production method, use

and concentration of the electrolyzed water, i.e. sanitizer. Too little or too much could make someone sick.

2017 FDA MODEL FOOD CODE CITATIONS

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

A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows:

- If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions; and
- If a chemical sanitizer is generated by a device located on-site at the food establishment it shall be used as specified in and shall be produced by a device that:
 - > Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - > Complies with 40 CFR 152.500 Requirement for Devices and 40 CFR 156.10 Labeling Requirements
 - > Displays the EPA device manufacturing facility registration number on the device
 - > Is operated and maintained in accordance with manufacturer’s instructions

7-204.11 Sanitizers, Criteria.

Chemical sanitizers, including chemical sanitizing solutions generated on-site, 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), or
- Meet the requirements specified in 40 CFR 180.2020 **Pesticide Chemicals** Not Requiring a Tolerance or an Exemption from a Tolerance-Non-food determinations.

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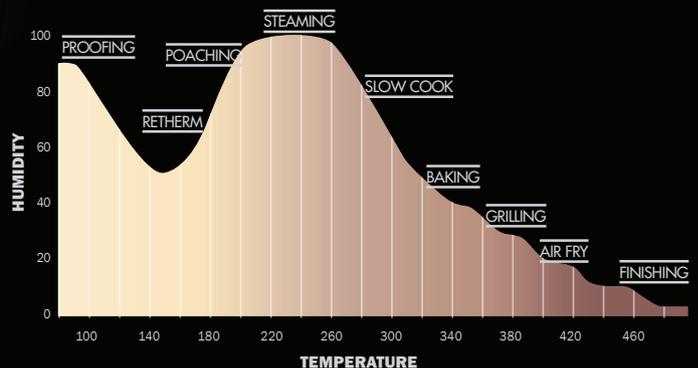


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7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.

Chemicals, including those generated on-site, used to wash or peel raw, whole fruits and vegetables or used in the treatment, storage, and processing of fruits and vegetables shall:

- Be an approved **food additive** listed for this intended use in 21 CFR 173, or
- Be generally recognized as safe (GRAS) for this intended use, or

> Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification), and

> Meet the requirements in 40 CFR 156 **Labeling Requirements for Pesticides and Devices.**

SUMMING IT UP

If you're considering making chemical sanitizing solutions on-site, make sure you and your foodservice employees follow proper procedures that ensure sanitization, but are not harmful to clients or staff. **E**

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This Level II article assumes that the reader has a foundation of basic concepts of the topic. The desired outcome is to enhance knowledge and facilitate application of knowledge to practice.

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1. An on-site device to generate hard surface sanitizers must be registered with the EPA as a(n)
 - A. Chemical producing device
 - B. Pesticide producing device
 - C. EPA registered unit
2. A sanitizer produced by an on-site generating device is made by technology known as
 - A. Electrolyzed water
 - B. Electrocutated water
 - C. Chemically treated water
3. A report from the manufacturer should clearly identify
 - A. The concentration of ingredients required
 - B. The concentration of the initial water used
 - C. The minimum acceptable concentration of active ingredient required
4. The equipment user should look to the equipment manufacturer for data to validate the _____ of the solution that is produced by the device as well as the conditions for the use of the solution.
 - A. Effectiveness
 - B. Cost
 - C. Risk
5. If used to wash fruits and vegetables, the on-site produced sanitizer must be:
 - A. Approved by FDA and be on the pesticide use list
 - B. Listed as an approved food additive and be GRAS
 - C. GRAS and on the pesticide use list
6. Chemical sanitizers are considered in the Food Code as
 - A. Poisonous materials
 - B. Toxic materials
 - C. Both A and B
7. The data plate on the sanitizer generating device must include
 - A. The date the equipment was manufactured
 - B. The EPA device manufacturing facility registration number
 - C. The EPA pesticide number

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