

Terminology, Jurisdictions, and Definitions

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Terminology	Definition	Reference	Comments
Washing	To cleanse, using water or other liquid, usually with soap or detergents by immersing, dipping, or scrubbing.	Free Dictionary online	
	N/A	EPA	EPA does not define washing
	<i>3-302.15 Washing Fruits and Vegetables-</i> To remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in READY-TOEAT form.	2013 FDA Food Code 3-302.15	Actual definition of washing (or cleaning) does not exist in 2013 food code. See Annex attachment for further information.
Rinsing	To thoroughly remove debris or residues with potable water	Google	Rinsing not defined in 2013 food code or EPA.
Antimicrobial pesticide	Intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.	EPA Guidance and FIFRA	https://www.epa.gov/pesticide-registration/antimicrobial-pesticide-registration#what https://www.epa.gov/pesticide-registration/what-are-antimicrobial-pesticides https://www.gpo.gov/fdsys/pkg/USCODE-2013-title7/html/USCODE-2013-title7-chap6-subchapII-sec136.htm
Sanitize	To control or reduce micro-organisms from inanimate surfaces	EPA	https://www.epa.gov/pesticide-registration/what-are-antimicrobial-pesticides
Sanitizer	Agent that reduces the number of bacterial contaminants to safe levels as judged by public health requirements. Commonly used with substances applied to inanimate objects. According to the protocol for the official	CDC	https://www.cdc.gov/hicpac/Disinfection_Sterilization/19_00glossary.html https://www.cdc.gov/infectioncontrol/guidelines/Disinfection/index.html

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	sanitizer test, a sanitizer is a chemical that kills 99.999% of the specific test bacteria in 30 seconds under the conditions of the test.		
Sanitization	Application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.	2013 FDA Food Code 1-201.10	Note: Non-food contact = 3 logs (EPA)
Disinfection	To destroy or irreversible inactivate fungi or bacteria	EPA	https://www.epa.gov/pesticide-registration/what-are-antimicrobial-pesticides
RAC - Raw Agricultural Commodity	Raw agricultural commodities include, among other things, fresh fruits, whether or not they have been washed and colored or otherwise treated in their unpeeled natural form; vegetables in their raw or natural state, whether or not they have been stripped of their outer leaves, waxed, prepared into fresh green salads, etc.; grains, nuts, eggs, raw milk, meats, and similar agricultural produce. It does not include foods that have been processed, fabricated, or manufactured by cooking, freezing, dehydrating, or milling.	EPA	40 CFR 180.1
	Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.	FD&C Act Section 201(r)	
Ready to Eat (RTE)	Food that is in edible form without further preparation.	2013 Food Code (1 201.10 a-i)	See attachment.
Food Processing Facility/ Plant	Facilities where processing of food occurs.	FDA guidance	http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm077256.htm

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	A commercial operation that manufactures, packages, labels, or stores FOOD for human consumption, and provides FOOD for sale or distribution to other business entities such as FOOD PROCESSING PLANTS or FOOD ESTABLISHMENTS.	2013 Food Code	2013 Food Code also defines food processing plant and exempts food retail establishments.
Processed Food	Food subject to the activities of canning, freezing, cooking, pasteurization or homogenization, irradiation, milling, grinding, chopping, slicing, cutting or peeling.	FDA Guidance	<u>The following activities do not constitute the processing of food:</u> Washing , waxing, coloring, hydro-cooling, refrigeration, shelling of nuts, ginning of cotton, and the removal of leaves, stems, and husks. http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm077256.htm
	any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.	FD&C Act Section 201 (gg)	
Crisping	FDA does not have definition		
	PW industry doesn't like the term "crisping", prefers "re-crisping" to ensure portrayal that leafy greens are crisp initially.		
Re-crisping	FDA does not have definition		Commodity Specific Guidance for Leafy Greens discusses best practices for "re-crisping"* http://www.fda.gov/downloads/food/guidanceregulation/ucm169008.pdf *Not a FDA document
Drinking Water	(1) "Drinking water" means water that meets	2013 FDA Food	

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	<p>criteria as specified in 40 CFR 141 National Primary Drinking Water Regulations.</p> <p>(2) "Drinking water" is traditionally known as "potable water."</p> <p>(3) "Drinking water" includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.</p>	Code 1-201.10	
Food Contact Surface	<p>"Food-contact surface" means:</p> <p>(1) A surface of EQUIPMENT or a UTENSIL with which FOOD normally comes into contact; or</p> <p>(2) A surface of EQUIPMENT or a UTENSIL from which FOOD may drain, drip, or splash:</p> <p>(a) Into a FOOD, or</p> <p>(b) Onto a surface normally in contact with FOOD.</p>	2013 FDA Food Code 1-201.10	Also referred to as "hard food contact surfaces". EPA regulated application.
Food Contact Surface Sanitizer	An antimicrobial/sanitizer used on a hard food contact surface.		
Food Contact Substance	A food contact substance is any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food, if such use is not intended to have any technical effect on such food	FDA Guidance	http://www.fda.gov/RegulatoryInformation/Guidances/ucm077256.htm (FFDCA § 409(h)(6))
Food Contact	A food contact substance, as above, used as	FDA Guidance	Excluded from the definition of "pesticide"

Terminology, Jurisdictions, and Definitions

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Substance Antimicrobial	a sanitizer/antimicrobial directly in/on food.		chemical" under 201(q)(1)(B)(i) of the FDCA, as amended by ARTCA, are antimicrobial substances applied on food, or added to water that comes into contact with the food in the preparing, packing, or holding of food for commercial purposes.

Terminology, Jurisdictions, and Definitions

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EPA/FDA Jurisdiction Table Antimicrobials Treatments (Food Use)

Category	Jurisdiction	Comments
Treatment of RAC's except in a food processing facility	EPA	
Treatment of RAC's during transportation to or in a food processing facility	EPA/FDA	
Consumer treatment of RAC's	EPA	
Post-harvest (in the field) treatment of RAC's	EPA	
Treatment of process water in food processing facility	EPA/FDA	
Treatment of processed food	FDA	
Crisping	?	Depends on product use/claims/intent.
On site generation of chemicals	EPA	EPA regulates device

FOOD CODE

Regulation	Code Reference	Comments
(A) Except as specified in ¶ (B) of this section and except for whole, raw fruits and vegetables that are intended for washing by the CONSUMER before consumption, raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in READY-TOEAT form. (B) Fruits and vegetables may be washed by using chemicals as specified under § 7-204.12. (C) Devices used for on-site generation of chemicals meeting the requirements specified in 21 CFR 173.315, Chemicals used in the washing or to assist in the peeling of fruits and vegetables,	§ 3-302.15	

Terminology, Jurisdictions, and Definitions

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<p>for the washing of raw, whole fruits and vegetables shall be used in accordance with the manufacturer's instructions.</p>		
<p>See also Annex listing below.</p>		
<p>Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.</p>	<p>§ 7-204.12; § 7-204.12 Annex 2 – References</p>	<p>(A) Chemicals, including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall: (1) Be an approved food additive listed for this intended use in 21 CFR 173, P or (2) Be generally recognized as safe (GRAS) for this intended use, P or (3) Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification), P and (4) Meet the requirements in 40 CFR 156 Labeling Requirements for Pesticide and Devices. 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.</p>

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		Annex 2 – References 2. Code of Federal Regulations, Title 21, Part 173.405, Secondary Direct Food Additives Permitted in Food for Human Consumption; Sodium Dodecylbenzenesulfonate.
See also Annex listing below.		

Annex 3

3-302.15 Washing Fruits and Vegetables.

Pathogenic microorganisms, such as *Salmonella* spp., and chemicals such as pesticides, may be present on the exterior surfaces of raw fruits and vegetables. It has been assumed that washing removes the majority of organisms and/or chemicals present; however, more recent studies have demonstrated washing to fall short of their complete removal. Biofilm development by *Salmonella* allows bacterial cells to survive under adverse environmental conditions and also reduces the ability to remove pathogens by washing, even with antimicrobial agents. All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed under running, potable water or with chemicals as specified in Section 7-204.12, or both, before eating, cutting or cooking. Even if you plan to peel or otherwise alter the form of the produce, it is still important to remove soil and debris first.

Infiltration of microorganisms can occur through stem scars, cracks, cuts or bruises in certain fruits and vegetables during washing. Once internalized, bacterial pathogens cannot be removed by further washing or the use of sanitizing solutions. To reduce the likelihood of infiltration, wash water temperature should be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is recommended that soaking or submerging produce during cleaning be avoided. It is important to follow practices that minimize pathogens in the water or on the surface of produce. It is important that proper handwashing procedures are followed, in accordance with Section 2-301.12 Cleaning Procedure, before and after handling fresh produce.

Scrubbing with a clean brush is only recommended for produce with a tough rind or peel, such as carrots, cucumbers or citrus fruits that will not be bruised easily or penetrated by brush bristles. Scrubbing firm produce with a clean produce brush and drying with a clean cloth towel or fresh disposable towel can further reduce bacteria that may be present. Washing fresh fruits and vegetables with soap, detergent or other surfactants should be avoided as they facilitate infiltration and may not be approved for use on food. Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations. Unless otherwise stipulated in 21 CFR 173.315, chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to any indications as dictated on the product label.

Terminology, Jurisdictions, and Definitions

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Many pre-cut, bagged produce items are pre-washed. If so, these products will be identified as such on the package label, and can be used as ready-to-eat without further washing. The label should also state if further washing is recommended or necessary. Precut or prewashed produce in open bags should not be washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are considered time/temperature control for safety food (TCS) requiring time/temperature control for safety and should be refrigerated at 41°F or lower to prevent any pathogens that may be present from multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and other produce, you may consult the FDA Program Information Manual, Retail Food Protection Storage and Handling of Tomatoes, dated October 5, 2007, available at

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm>, the document, Time as a Public Health Control for Cut Tomatoes, dated June 8, 2010 available at

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm215053.htm>

and the FDA Program Information Manual, Recommendations for the Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments dated July 7, 2010 available at

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm218750.htm>

On October 26, 1998 a voluntary guidance document for the produce industry which addresses microbial hazards and good agricultural and management practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents and was updated on August 19, 2003. This “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”, October 26, 1998, is available from FDA’s Food Safety Initiative staff and also on the Internet at

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064574.htm>.

Additionally, in February 2008, the FDA Center for Food Safety and Applied Nutrition (CFSAN) issued “Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,” which covers fresh-cut fruits and vegetables that have been minimally processed (e.g. no kill step) and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. This guide is available at:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm>.

On January 11, 2006 FDA/CFSAN published additional safe handling advice on the purchase, storage, and preparation of fresh produce, as well as Q & A’s for consumers on their website at: <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm114299.htm>. This document is available in PDF (3.5 MB) format (also available in Spanish) and provides additional information on the cleaning of fresh produce.

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7-204.12 Chemicals for Washing Fruits and Vegetables

If the chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are approved food additives or food-contact substances, generally recognized as safe, prior sanctioned or exempted by the threshold of regulation process can be used. Information regarding food contact substances notification may be found on the FDA website under the Food Topic in Ingredients and Packaging section at:

<http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm>

Chemicals that are not generally recognized as safe, or not authorized by FDA for these uses may be submitted for review by filing a Food Additive Petition, a Food Contact Notification (FCN), or a request for exemption under the Threshold of Regulation. Wash chemicals, boiler water additives, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR. If the chemicals are hard food-contact sanitizers, or washes for raw agricultural commodities (RACs) that are used on a farm or in a packing house, then this is under the jurisdiction of the EPA.

21 CFR 173 Secondary Direct Food Additives Permitted in Food for Human Consumption includes a number of regulations permitting certain food additives to be used for washing fruits and vegetables. In an effort to be consistent with federal law a change was made in Section 7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria to include all of 21 CFR 173 so as not to exclude the use of other permitted food additives. There is also another mechanism for approval of antimicrobial agents for washing fruits and vegetables (i.e., the food contact notification program) as well as GRAS ingredients permitted as antimicrobials or for general food use. This revision allows for the use of ingredients that are GRAS for this use and food contact substances which were the subject of an effective food contact notification for this use. 21 CFR 173 includes permitted food additives such as those listed in 21 CFR 173.315 Chemicals used in the washing or to assist in the peeling of fruits and vegetables. This section specifically identifies some of the chemicals that may be used in washing fruits and vegetables, regardless of whether the chemicals are commercially produced or generated on site. Sodium hypochlorite is listed in 21 CFR 173.315 for use in washing fruits and vegetables at levels not exceeding the minimum amount required to accomplish the intended technical effect. FDA has no objection to the use of calcium hypochlorite in the place of sodium hypochlorite under 21 CFR 173.315.

On December 4, 2012, the FDA amended the food additive regulations to provide for the safe use of sodium dodecylbenzenesulfonate (SDBS) (CAS No. 25155-30-0) as an antimicrobial agent for use in wash water for fruits and vegetables without the requirement of a potable water rinse. 21 CFR Section 173.405 specifically identifies this additive as an antimicrobial agent used in wash water for fruits and vegetables. The additive may be used at a level not to exceed 111 milligrams per kilogram in the wash water. Fruits and vegetables treated by the additive do not require a potable water rinse. Use of this additive is limited to use in commissaries, cafeterias, restaurants, retail food establishments, nonprofit food establishments and other food service operations in which food is prepared for or served directly to the consumer. To ensure safe use of the additive, refer to the label or labeling of the additive and/or antimicrobial pesticide container for adequate

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directions. Information on the label is required in accordance to provisions within 21 CFR 173.405 and the Federal Food, Drug and Cosmetic Act. Although the petitioned use of SDBS is regulated under Section 409 of the FD & C Act as a food additive, this intended use of SDBS may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA requirements pertain to EPA registered pesticide products that have uses subject to EPA or both FDA and EPA regulations. Therefore, manufacturers intending to use this food additive for this intended use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

Boiler water additives that may be safely used in the preparation of steam that may contact food, and their condition of use, are identified in 21 CFR 173.310 Boiler Water Additives.

Additional resources:

1. <https://www.khlaw.com/701>
2. Determining Regulatory Authority for Antimicrobial Substances. Decision Tree for Determining whether any Particular Antimicrobial Intervention for Food is Regulated by the Environmental Protection Agency or the Food and Drug Administration <https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryAuthorityAntimicrobialSubstances/default.htm>