CLEANERS AND SANITIZERS APPROPRIATE FOR USE IN A FOOD PROCESSING ENVIRONMENT

Prepared by
William C. Balek
International Sanitary Supply Association
March 30, 2001

I INTRODUCTION

In the wake of the discontinuation of the USDA authorization program, we are left with the question as to how do we define cleaners and sanitizers that are considered to be safe when used in a food processing environment.

In fact there are several sources that we can refer to in defining such products. This outline examines such sources and provides summaries of the guidance they provide in regard to nonfood compounds such as cleaners and sanitizers. Specific publications that are referenced in this document include:

- Sanitation Performance Standards Guide (FSIS)
- Guidelines for the Authorization of Nonfood Compounds (FSIS)
- 1999 Model Food Code (FDA)

II USDA/FSIS GUIDANCE

A. General Standards (Sanitation Performance Standards Guide)

1. Meat and poultry establishments are responsible for ensuring the safety and efficacy of nonfood compounds (i.e., cleaners and sanitizers).

2. Nonfood compounds should not adulterate meat or poultry or lead to conditions of insanitation.

3. Nonfood compounds should not create or lead to inspection interference. For example, processing compounds that mask odors, or pine cleaners that leave lingering odors, interfere with the ability of inspection personnel to detect pockets of insanitation.

3. Product labeling from suppliers should clearly provide identity of product, address of manufacturer or supplier, and intended use.

4. Materials that are: known human carcinogens; mutagens or teratogens; heavy metals; or hazardous compounds classified as "extremely toxic" should not be allowed in the plants.

B. Cleaning Compounds

1. Categories of Cleaning Compounds. The requirements described below apply to all of the following cleaning products:

a) General Use (A1). These products are used for general cleaning on all surfaces, or for use with steam or mechanical cleaning devices in all departments. They are typically neutral or mildly alkaline preparations consisting of any combination of soaps, detergents, wetting agents, emulsifiers, solubizers, and common inorganic builders.

b) Soak Tanks (A2). These compounds are designed for use only in soak tanks or with steam or mechanical cleaning devices in all departments. They are generally strongly alkaline preparations containing in excess of 20% caustic soda or other ingredients with the equivalent causticity.

c) Acid Cleaners (A3). This product category consists of acidic preparations consisting of mineral acids, organic acids, or acidic salts. Such products may be used in any department for the removal of rust, corrosion, scale, or other deposits, which are not readily removed by alkaline preparations.

d) Floor and Wall Cleaners for all Departments (A4). This category consists of general use floor and wall cleaners for use in all departments.

e) Floor and Wall Cleaners for Subfreezing Temperatures (A5). Glycol or alcohol based cleaners may be used on floors and walls in areas with subfreezing temperatures.

f) Scouring Cleaners (A6). This category generally consists of products containing abrasive materials such as silica, pumice, etc.

g) Metal Cleaners and Polishes for Nonfood Contact Surfaces (A7). In general, these products are water based or solvent based metal cleaners and polishes designed for use on nonfood contact surfaces for removing and/or preventing corrosion.

h) Degreasers or Carbon Removers (A8). These products are generally used on food cooking equipment, smoking equipment, utensils, or other associated surfaces.

i) Cleaning and Degreasing Solvents for Use in Nonprocessing Areas (K8)

2. Standards—Sanitation Performance Standards Compliance Guide

a) Cleaners should be formulated to be safe and appropriate for the intended use.

b) Cleaners should not contain undesirable microorganisms.

c) Cleaners should be formulated so that rinsing will be sufficient to ensure effective removal of cleaning solution from food contact surfaces and removal of residual odors from food processing areas.

d) Use of special purpose cleaners classified as hazardous materials should be limited to the amount and frequency only sufficient for the required effect. Use only in accordance with manufacturer's labeling instructions and precautions.

e) Use of hazardous substances containing fluorine compounds, such as hydrofluoric acid, hydrofluosilic acid, or ammonium bifluoride, to remove siliceous scale deposits or for similar cleaning purposes should be documented and the substance should not be stored in the plant. They should also be used in accordance with paragraph (d).

f) Cleaners consisting primarily of hydrocarbon, chlorinated hydrocarbon or other water immiscible solvents should be limited to use in non-processing areas. Treated food processing equipment and utensils should be washed and thoroughly rinsed with potable water before being returned to a processing area.

g) Cleaners formulated to provide low freezing points such as alcohol or glycol based compounds are appropriate for use on surfaces that do not contact food in areas in subfreezing temperatures. The cleaning solution and solubilized soil should be effectively removed by wiping, wet vacuuming, or other appropriate means.

h) Boric acid and salts thereof should be limited to 90% of a cleaner in association with strong acids, strong alkalis, soaps or synthetic detergents.

i) General use cleaners should not have an expected human single oral LD50 of < 10mg/kg.

3. Restrictions of Use—General Guidelines for the Authorization of Nonfood Compounds

a) Before using any cleaning preparation in food processing areas, food products and packaging materials must be removed from the room or

carefully protected. After using such preparations, all surfaces must be thoroughly rinsed with potable water.

b) Preparations having a characteristic odor or fragrance as diluted for use that may interfere with the sanitary inspection of food contact surfaces may not be used on food contact surfaces. However, such products may be authorized for limited use on floors and walls or to degrease and remove carbon from food cooking or smoking equipment, utensils, and other similar surfaces. These preparations must be used in a manner so that all odors associated with the compounds are dissipated before food products or packaging materials are re-exposed in the area.

c) Preparations containing abrasive materials such as silica, pumice, etc. may be used on food contact surfaces only if care is taken to remove all odors or residues resulting from their use by thoroughly rinsing with potable water.

d) Metal cleaners and polishes may be used on nonfood contact surfaces only if they are used in a manner so that all odors associated with the compounds are dissipated before food products or packaging materials are re-exposed to them.

C. Sanitizers and Disinfectants.

1. Product Categories.

a) Antimicrobial agents that always require a rinse (D1)

b) Sanitizers for all surfaces which do not always require a rinse (D2)

2. Standards—Sanitation Performance Standards Compliance Guide

a) Chemical sanitizers and other chemical antimicrobials used on food contact surfaces must comply with the 21 CFR Section 178.1010 or appropriate food additive regulations.

b) Chemicals used to sanitize food contact surfaces and utensils must comply with 21 CFR 178.1010.

c) Sanitizers should only be applied to cleaned surfaces. Sanitized food contact equipment and utensils must be adequately drained, in accordance with 21 CFR 178.1010, sufficient to prevent food adulteration.

d) EPA registered antimicrobials must include labeling instructions stating that they are appropriate for use in food establishments.

e) Chemical germicides established as meeting the efficacy requirements of EPA as both a hospital level disinfectant and a tuberculocide are appropriate for use to decontaminate implements provided:

- Food contact surfaces are subsequently washed and rinsed;
- Appropriate preventative actions are taken to protect edible products and food packaging materials; and
- Labeled use directions specify minimum contact time required to meet both registered kill levels.

f) Antimicrobial solutions should be kept free of contamination and maintain effectiveness under intended conditions of use.

g) Chemical sanitizers should be EPA registered for sanitizing food contact surfaces or otherwise established to provide germicidal efficacy yielding a 5-log10 reduction of representative disease microorganisms of public health importance.

h) Chemical sanitization of food contact surfaces should ensure exposure times of at least 10 seconds for chlorine solutions or at least 30 seconds for other chemical sanitizer solutions, or according to EPA registered use directions for food contact surfaces.

i) A chlorine sanitizing solution should have a minimum temperature based on the concentration and pH of the solution as listed in the following chart; or as specified under EPA registered label use instructions.

Minimum Concentration MG/L(mg/L)	**Minimum Temperature (°F)**	
	PH of 10 or less	**pH of 8 or less**
25	**120**	**120**
50	**100**	**75**
100	**55**	**55**

3. Guidelines for the Authorization of Nonfood Compounds

a) Sanitizers—Equipment and Utensils (hard non-porous food contact surfaces). Sanitizing solutions may be used on hard non-porous food contact surfaces such as equipment and utensils without a subsequent potable water rinse provided they are formulated in compliance with 21 CFR 178.1010 and are registered with EPA. The sanitizers must be used as follows:

- Such surfaces are thoroughly drained and any collection of liquid removed therefrom before contact with food products is made.

- The sanitizing solutions are used in accordance with label directions.

b) Sanitizers—Equipment and Utensils (porous and semi-porous food contact surfaces). Concentrations of hypochlorite solutions considerably higher than those described provide in 21 CFR 178.1010 (b)(1)(a) are necessary to provide efficacy in sanitizing porous and semi-porous surfaces such as wood.

A 600 ppm available chlorine solution may be used, maintaining contact for at least two minutes. The equipment or utensils must be rinsed with a 200 ppm available chlorine solution prior to use.

c) Sanitizers—Ceilings, floors, and walls. Sanitizing solutions described in 21 CFR 178.1010 (b) may be used on such surfaces at concentrations considerably higher than those described in 21 CFR 178.1010 (c), without a potable water rinse unless, in the judgment of the inspector, each use results in residues which may contaminate food products subsequently processed or be otherwise objectionable

Other antimicrobial solutions must be followed by a potable water rinse.

d) Disinfectants. The use of disinfectants on hard non-porous food contact surfaces, such as equipment and utensils, must be followed by a potable water rinse. Such solutions must be used in a manner which does not result in contamination of food products subsequently processed and must be consistent with the directions on the EPA registered label.

D. Compounds for Laundry Use.

1. Sanitation Performance Standards Compliance Guide

a) Labeling should include appropriate use directions.

b) Laundry compounds should be formulated so that rinsing instructions will be sufficient to prevent food contamination or inspection interferences, and to ensure effective removal of laundry agents from food contact articles (e.g., carcass shrouds).

2. Guidelines for the Authorization of Nonfood Compounds

a) For all Fabrics—Preparations consisting of soaps, synthetic detergents, alkaline builders, or any combination thereof are permitted for laundering

shrouds or other fabrics used in the plant which may contact meat or poultry products directly or indirectly. Fluorescent dyes or optical brighteners may also be added if there is sufficient information on them to assure their safe use.

Sours consisting of acetic acid, sodium bisulfate or other acceptable acidic materials are permitted to neutralize excess alkalinity in all laundered fabrics. Chlorine or oxygen bleaches are permitted to remove stains or maintain whiteness of all fabrics. The presence of a perfume or other odorant in a preparation may exclude its use on shrouds or other fabric which directly or indirectly contact meat or poultry products.

In all cases, the final operation of the laundry cycle must be a potable water rinse sufficient to remove all added substances from the laundered fabric.

b) Fabrics Not in Direct Contact With Food—In addition to the above description, fabric softeners or antistatic agents and starches may be used on uniforms or other fabrics which do not come into direct contact with food products. A perfume or other odorant may be used in these laundry compounds.

E. Employee Hand Care Products

1. Product Categories

a) Hand washing compounds for use in all departments (E1)

b) Hand washing and sanitizing compounds (E2)

c) Hand sanitizing compounds (E3)

d) Hand creams, lotions, and cleaners (E4)

2. Standards—Sanitation Performance Standards Compliance Guide

a) Hand care products formulated with chlorhexidene gluconate and intended to be used as an antimicrobial hand cleaner or hand sanitizer/dip in food handling and processing are considered a "drug" and possibly "new drug" under the Federal Food, Drug and Cosmetic Act (FFDCA).

These products are subject to registration by the FDA, OTC compliance branch before they can be marketed and used.

b) Hand care treatments intended for use as a "barrier" or "shield" to prevent or mitigate human disease by protecting skin from exposure to

toxic chemicals and/or pathogenic microorganisms are considered "drugs" and possibly "new drugs" under the FFDCA. As such these products are subject to registration by the FDA before they can be marketed and used.

c) Hand treatments intended to remain on the hands of handlers should be formulated in compliance with the appropriate food additive regulations, 21 CFR 178.1010, or appropriate GRAS regulations.

d) Hand sanitizer solutions should be kept clean and maintained at a germicidal equivalence of at least 50 ppm available chlorine as hypochlorite at 68°F for one minute.

e) Precautions should be taken to ensure hand care stations do not cause direct or indirect contamination of food or food contact surfaces with hand care substances.

Therefore, FSIS recommends that only liquid hand cleaners and sanitizers in appropriate dispensing devices be used in areas where food and food contact surfaces are exposed.

f) Hand treatments not formulated in compliance with appropriate food additive regulations should be:

- Thoroughly removed from the hands by rinsing in clean potable water, or

- Separated from contact with food by the use of gloves that are an effective barrier to migration of the nonfood substance to edible product.

3. Guidelines for the Authorization of Nonfood Compounds

a) Powdered or abrasive hand cleaners in suitable dispensing devices may be used in toilets, employee dressing rooms and other nonprocessing areas. Such cleaners may contain up to 90% sodium borate (borax), or other abrasive material, in combination with soaps or detergents and other adjuvants common to such preparations.

b) Waterless hand cleaners and hand lotions or creams may also be used in toilets, employee dressing rooms or other nonprocessing areas. However, employees who handle food products may use them only when leaving the plant for the day.

c) Those solutions described in 21 CFR 178.1010 which are applicable for the purpose may be used to sanitize the hands of employees handling food products without a subsequent rinse provided they are germicidally

equivalent to 50 ppm chlorine. (Protocol for gathering data supporting germicidal equivalency claim of 50 ppm available chlorine shall be consistent with Section 5.3(B) of the Guidelines for the Authorization of Nonfood Compounds.)

Hand sanitizing is not a substitute for hand washing. Accordingly, such sanitizing solutions may be used only after thoroughly washing hands with soap or detergent and water, followed by rinsing with potable water.

d) Combination detergent-germicides (single-step preparations designed to combine hand washing and sanitizing) will be considered for authorization on the basis of their ability to effectively clean the hands as well as their germicidal equivalency to 50 ppm available chorine.

The hands need not be washed with soap or detergent prior to use of such preparations. However, the hands must be rinsed with potable water after the use of the preparations and before handling food.

e) Preparations that leave a residual fragrance on the hands after rinsing which may interfere with the inspection of food product, may not be used in food processing areas or by employees who handle food products.

F. Water Treatments

1. Product Categories

a) General potable water treatment compounds (G1)

b) Phosphate potable water treatment (G2)

c) Silicate potable water treatment compounds (G3)

d) Chlorine potable water treatment (G4)

e) Cooling and retort water treatment (G5)

f) Compounds for treating boilers, steam lines, where the steam produced may contact edible products and/or cooling systems where the treated water may not contact edible products (G6)

g) Compounds for treating boilers, steam lines, and/or cooling systems where neither the treated water nor the steam produced may contact edible products (does not include compounds added to water used to cook and cool containers of meat and poultry products.

2. Standards—Sanitation Performance Standards Compliance Guide

a) Boiler water treatments where the steam may contact food must be formulated in compliance with 21 CFR 173.310.

b) Ion-exchange resins used for water purification must be formulated in compliance with 21 CFR 173.25.

c) Additives used in water in which fruits and vegetables are washed must be formulated in compliance with 21 CFR 173.315 and defoamers found in 21 CFR 173.340(a)(2).

d) Additives used in water for preflushing of animal casings must be GRAS.

e) Processing additives are appropriate for use provided that the quantities of these compounds are controlled, monitored, and limited to the amount sufficient for the purpose of such use.

f) Processing additives for potable water treatments should be composed of appropriate substances which are prior sanctioned by FDA or GRAS, and limited to the following:

- In potable water, phosphate should not exceed 10 ppm, silicate should not exceed 10 ppm, and chlorine should not exceed 5 ppm.

- In other processing applications, chlorine should not exceed 50 ppm in carcass wash and 20 ppm on trimmed or reprocessed poultry carcasses.

g) Compounds containing the sodium or potassium salts of nitrate, sulfate, bisulfite, or metabisulfite should be decharacterized so their effect on the heme pigments in meat products is prevented. Decharacterization may be achieved by the addition of colorant to prevent mishandling or by other means such as creation of a basic environment to prevent the formation of acid species of these additives,

h) Additives containing nitrite, borate, and nitrate containing treatments for nonprocessing water should be colored distinctively (traditionally blue or green) to avoid accidental misuse.

III FDA MODEL FOOD CODE

A. Hand Sanitizers

1. A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall comply with one of the following:

a) Be an approved drug that is listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations as an approved drug based on safety and effectiveness; or

b) Have active antimicrobial ingredients listed in the:

- FDA monograph for OTC health care antiseptic drug products as an antiseptic handwash; or
- The USDA List of Proprietary Substances and Nonfood Compounds; **and**

2. Comply with one of the following:

a) Have components that are exempted from the requirement listed in the FDA food additive regulations as specified in 21 CFR 170.39 (threshold of regulation for substances used in food contact articles); or
b) Comply with and be listed in:

- 21 CFR 178—Indirect Food Additives: Adjuvants, Production Aids and Sanitizers as regulated for use as a food additive with conditions of safe use; or
- 21 CFR 182—Substances Generally Recognized as Safe, 21 CFR 184—Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186—Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food; **and**

3. Be applied only to the hands that are cleaned as specified under Section 2-301.12 of the MFC.

4. If a hand sanitizer or a chemical hand sanitizing solution used as a hand dip does not meet the criteria specified in paragraph 2 above, the use of such hand sanitizer shall be:

a) Followed by a thorough hand rinsing in clean water before hand contact with food or by the use of gloves; or

b) Limited to situations that involve no direct contact with food by the bare hands.

5. A chemical hand sanitizing solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 11mg/L chlorine.

B. Sanitizers

Chemical sanitizers and other chemical antimicrobials applied to food contact surfaces shall meet the requirements specified in 21 CFR 178.1010 for sanitizing solutions.

C. Boiler Water Additives

Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310 (Boiler Water Additives).

D. Drying Agents

Drying agents used in conjunction with sanitization shall:

1. Contain only components that are listed as one of the following:

a) Generally recognized as safe for use in food as specified in 21 CFR 182—Substances Generally Recognized as Safe; or 21 CFR 184—Direct Food Substances Affirmed as Generally Recognized as Safe;
b) Generally recognized as safe for the intended use as specified in 21 CFR 186—Indirect Food Substances Affirmed as Generally recognized as Safe;

c) Approved for use as a drying agent under a prior sanction specified in 21 CFR 181—Prior Sanctioned Food Ingredients;

d) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175-178; or

e) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 threshold of regulation of substances used in food contact articles; **and**

2. When sanitization is with chemicals, the approval required under paragraphs 1(c) or 1(e) above or the regulation as an indirect food additive required under 1(d) above, shall be specifically for use with chemical sanitizing solutions.

E. Chemicals for Washing Fruits and Vegetables

Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315.

IV SHELL-EGG CLEANERS AND SANITIZERS

A. Sanitizers. EPA has issued guidance for the use of food-grade shell-egg sanitizers as follows.

1. All formulations must be cleared under 21 CFR 178.1010 as a sanitizer for food contact surfaces, **or** have a tolerance/exemption from the requirement of a tolerance in 40 CFR Part 180.

2. Any reference/directions for use for eggs intended for use as hatchlings is a drug claim and is regulated only by the FDA.

3. Only clean, whole eggs can be used for sanitizing. Dirty, cracked or punctured eggs cannot be sanitized

4. If the product is intended for use as both a cleaner and a sanitizer, separate directions for use as a cleaner must be provided and followed by a potable water rinse, preceding the directions for use as a sanitizer with a fresh solution.

5. The "directions for use" must be similar to the following:

"To sanitize clean shell eggs intended for food or food products, spray with a solution of **x** ounces of product in **x** gallons of water (providing **x** ppm active). The solution must be equal to or warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. (INSERT STATEMENT (a), (b), or (c) below as appropriate). Eggs must be reasonably dry before casing or breaking. The solution must not be reused for sanitizing eggs."

a) "Eggs that have been sanitized with this **quaternary ammonium** compound shall be subjected to a thorough potable water rinse only if they are to be immediately broken for use in the manufacture of egg products."

b) "Eggs that have been sanitized with this **chlorine** compound may be broken for use in the manufacture of egg products without a prior potable water rinse."

c) "Eggs that have been freshly washed may be sanitized with this **iodine** compound only if the eggs are rinsed prior to application of the compound. A subsequent potable water rinse is not required."

6. The inclusion of a labeling claim for use in federally inspected meat and poultry facilities must be done through an amendment (i.e., "This product can be used in Federally Inspected Meat and poultry Facilities as a sanitizer.").

B. Cleaners. Guidelines used by the USDA under the now defunct authorization program provide some guidance on products used to clean shell-eggs as set forth below.

1. Shell-eggs may not be allowed to stand or soak in water. Immersion-type washers are not permitted.

2. Washed shell-eggs must be spray rinsed with warm potable water containing an accepted sanitizer.

3. Destaining of shell-eggs is permitted only after initial washing of the shell eggs is completed. The total time of the shell-eggs in the destainer solution may not exceed 5 minutes. After destaining, shell-eggs must be rewashed and spray rinsed with warm potable water containing an accepted sanitizer.