

solutions are described in 21 CFR 178.1010:

- Those used on food-contact surfaces in public eating places.
- Those used on dairy-processing equipment.
- Those used on food-processing equipment and utensils.

According to FDA, food-contact surface sanitizing solutions that are acceptable for use on food-contact surfaces in public eating places can also be used on dairy-processing equipment, and on food-processing equipment and utensils. Food-contact surface sanitizing solutions that are acceptable for use on dairy equipment can also be used on food-processing equipment and utensils. EPA has separated the component ingredients by both chemical and concentration for these three types of food-contact surface sanitizing solutions, which will be included in 40 CFR 180.940.

IV. Issuance and Withdrawal of Direct Final Rule

In the **Federal Register** of December 3, 2002 (67 FR 71847) (FRL-6824-2), the Agency published a direct final rule to establish 40 CFR 180.940. Comments were received. In the December 3, 2002 **Federal Register** notice, EPA announced that it would withdraw the direct final rule if it received adverse comment, and proceed with proposed rule as provided by section 553 of the Administrative Procedure Act, 5 U.S.C. 553. Because some of the comments were of a nature that would warrant a response if made on a proposed rule, they are adverse comments that require withdrawal of the direct final rule. Accordingly, EPA withdrew the direct final rule on March 24, 2003 (68 FR 14165) (FRL-7299-4).

Several of the comments reflected some understandable confusion on the part of the commenters. While EPA's chemical-specific approach and FDA's formulation specific approach are essentially equivalent, the two approaches look and read differently. EPA disaggregated the 46 formulations in 21 CFR 178.1010 into a list of chemicals. This list of chemicals was then subdivided into three separate lists based on use categories in 21 CFR 178.1010 (i.e., food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils). The 40 CFR 180.940(a) list contains only the chemicals specified in those formulations that were designated by FDA for use in public eating places. The 40 CFR 180.940(b) list contains only the chemicals specified in those formulations that were designated by FDA for use on dairy equipment. The 40

CFR 180.940(c) list contains all chemicals because all formulations in 21 CFR 178.1010 can be used on food-processing equipment and utensils.

The maximum concentration level for each chemical was determined by evaluating the range derived from the lists in 40 CFR 180.940(a), (b), or (c). Where 21 CFR 178.1010 authorized several different sanitizing solutions each containing a particular chemical, but at different concentrations, EPA will use only the highest concentration as the upper limit, reflecting FDA's implicit determination that concentrations up to and including that limit do not compromise food safety. As an example, if three solutions authorized under 21 CFR 178.1010 for use on dairy equipment contain chemical "X" at concentrations of 150, 200, and 240 parts per million (ppm), then 240 ppm would be used as the upper limit in 40 CFR 180.940(b). If for chemical "Y," concentrations of 150 and 200 ppm were specified, but in a third solution the concentration was not specified, then the upper limit for chemical "Y" in 40 CFR 180.940(c) would be specified as "none." This reflects FDA's implicit determination in regard to that third sanitizing solution that chemical "Y" could be used in any concentration without significant risk to food safety.

In addition to the disaggregation, the Agency also in some cases used a different chemical nomenclature. CI (chemical index) names and CAS Nos. were used to the greatest extent possible. This is part of an Agency-wide effort to provide a common and consistent way to identify and represent chemical substances across the Agency. Thus, sodium hypochlorite became hypochlorous acid, sodium salt. In other instances (most commonly involving polymers or quaternary ammonium compounds), FDA approved in one solution a particular chemical that falls within a more inclusive chemical designation approved in another solution. If practicable in such instances, EPA has stated the tolerance exemption only in terms of the more inclusive chemical designation, implicitly exempting all chemical substances that fall within that designation. For example, n-alkyl ($C_{12}-C_{16}$) benzyl dimethyl ammonium chloride would be considered to be a subset of n-alkyl ($C_{12}-C_{18}$) benzyl dimethyl ammonium chloride. Another example, n-alkyl ($C_{12}-C_{18}$) benzyl dimethyl ammonium chloride (mw 351 to 380) would also be considered a subset of n-alkyl ($C_{12}-C_{18}$) benzyl dimethyl ammonium chloride. Both of the example chemicals would be

accounted for under the nomenclature quaternary ammonium compounds alkyl ($C_{12}-C_{18}$) benzyl dimethyl, chlorides. For each comment questioning whether a particular chemical substance appeared in the direct final rule, the Agency was able to verify that the chemical for which the commenter expressed concern was included in 40 CFR 180.940, albeit under a different designation.

A commenter asked that instead of using the term "oxychloro species," that sodium chlorite or chlorine dioxide should be used instead. The "generated by" language was considered to be confusing in a listing of chemical names. The Agency (as acknowledged by the commenter) used FDA's language, which is an approach which describes the process for generating the solution, not the components of the solution. If the end-products of the generation process were specific chemicals already included in the other solutions (and therefore already line-items), then the Agency used the disaggregated approach. However, for the oxychloro species generation methods described in 21 CFR 178.1010(b)(34), the chlorite, chlorate, and/or chlorine dioxide is actually an equilibrium mixture. There are no separate line-item entries for these chemicals. In fact, the upper concentration limit is specified in terms of chlorine dioxide only, thus making it difficult to separate the chemicals into line items. The Agency determined therefore to maintain the original FDA language at this time. The Agency also considered that other generation methods for oxychloro species could be submitted as part of the non-designated prior approved chemical substances, which could impact the handling of this in the future.

Several commenters asked if a specific combination of quaternary ammonium compounds expressly identified in 21 CFR 178.1010(b)(22) were included in 40 CFR 180.940. Each of the component chemicals identified in 21 CFR 178.1010(b)(22) are identified in 40 CFR 180.940 as subject to a tolerance exemption. The two components listed in 21 CFR 178.1010(b)(22) are di-n-alkyl (C_8-C_{10}) dimethylammonium chloride (mw 332 to 361) and n-alkyl ($C_{12}-C_{18}$) benzyl dimethyl ammonium chloride (mw 351 to 380). The first chemical is listed in 40 CFR 180.940 as "Quaternary ammonium compounds, di-n-alkyl (C_8-C_{10}) dimethyl ammonium chloride average molecular weight (in amu) 332 to 361." 21 CFR 178.1010(b)(22) and 21 CFR 178.1010(c)(17) together allow a maximum end-use concentration of 400