

408 pesticide chemical tolerances or tolerance exemptions. This “grandfather” provision of FFDCA section 408(j) assures that pesticide chemical residues conforming to regulations issued under the authority of FFDCA section 409 will not render food adulterated as a result of the jurisdictional shift from FDA to EPA.

In 1998, ARTCA amended the definition of “pesticide chemical” in FFDCA section 201(q) so as to exclude certain antimicrobial pesticide residues from the authority of FFDCA section 408. Consistent with FFDCA section 408(j)(4), these residues now fall within the authority of FFDCA section 409. As a result, certain uses of food-contact surface sanitizing solutions identified in FDA’s regulations at 21 CFR 178.1010 remain subject to FFDCA section 409 regulations just as they did pre-FQPA, while other uses are now subject to EPA’s jurisdiction under FFDCA section 408.

*B. Why are these Tolerance Exemptions not Subject to Tolerance Reassessment at this Time?*

Under FFDCA section 408(q), EPA is required to reassess all tolerance exemptions that were in effect on the day before the enactment of the FQPA. The tolerance exemptions for inert ingredients as well as those active ingredients not yet completed will be reassessed in accordance with EPA’s schedule for tolerance reassessment published in the **Federal Register** of August 4, 1997 (62 FR 42019) (FRL–5734–6).

The tolerance exemptions in this proposed rule to be codified in 40 CFR 180.940 already exist as valid FFDCA section 408 regulations. FDA promulgated the food additive regulations in 21 CFR 178.1010 under the authority of FFDCA section 409 prior to the enactment of FQPA. By operation of FFDCA section 408(j)(2), those portions of 21 CFR 178.1010 that pertain to chemical substances that are pesticide chemicals post-FQPA and remain as such post-ARTCA were converted to FFDCA section 408 tolerance exemptions. EPA’s duplication of these tolerance exemptions is not “establishing, modifying, or revoking a tolerance” under FFDCA section 408(b). EPA is, therefore, not required to conduct a full reassessment of these tolerance exemptions at this time.

*C. Why is 40 CFR 180.940 being Created?*

The Agency is duplicating in 40 CFR 180.940 only those portions of the regulations in 21 CFR 178.1010 that

pertain to pesticide chemicals. This duplication will have no effect on any of FDA’s regulated FFDCA section 409 food additive regulations in 21 CFR 178.1010.

In establishing food additive regulations for food-contact surface sanitizing solutions in 21 CFR 178.1010, FDA used a formulation-specific approach. Consistent with its authority under FFDCA section 409, FDA issued regulations prescribing the conditions under which food-contact surface sanitizing solutions might be safely used. FDA approved the use of each food-contact surface sanitizing solution formulation as a whole, rather than regulating each component chemical substance individually. In addition, FDA included a generic exemption for any chemical substance considered to be GRAS, and in some cases, issued letters not objecting to certain additional chemical substances in the formulations.

By contrast, FFDCA section 408 authorizes EPA to issue regulations establishing tolerances or exemptions from the requirement of a tolerance. EPA’s practice has been to issue these regulations on a chemical-specific basis, whereby each ingredient in the product is the subject of a separate tolerance or exemption regulation. Food-contact surface sanitizing solutions meet the requirements of FFDCA if each ingredient has an appropriate clearance under FFDCA, either a tolerance or an exemption from the requirement of a tolerance, and any conditions on the clearance are observed.

Translating the regulatory decisions made by FDA into a comparable EPA scheme requires considerably greater work on EPA’s part than merely copying those portions of the existing regulations in 21 CFR 178.1010 that pertain to pesticide chemicals directly into 40 CFR 180.940. EPA must disaggregate the formulations in 21 CFR 178.1010 that pertain to pesticide chemicals into their component ingredients. EPA must also provide a mechanism to address those ingredients not identified by name in 21 CFR 178.1010 but that were, for example, permitted by prior sanction or approval, not objected to, or generally recognized as safe. This, in fact, places a higher initial demand on EPA resources than would be required to simply copy FDA’s approach. However, EPA is convinced that the long-term administrative convenience of using a consistent regulatory scheme for all pesticide chemicals subject to FFDCA section 408 outweighs the initial burdens.

FDA’s formulation-specific approach is different from EPA’s chemical-

specific approach. Under EPA’s approach, a tolerance exemption would be approved once for each particular pesticide chemical, and would not need to be repeated as new products containing that chemical substance enter the market. EPA’s approval process is not complex, will allow for a wide variety of potential products, and fosters innovative formulation approaches. In addition, by listing in one place (40 CFR 180.940) all chemical substances exempted from the requirement of a tolerance when used in food-contact surface sanitizing solutions, EPA’s approach will increase the transparency of its regulatory process.

This duplication will not allow any residues beyond those already permitted by 21 CFR 178.1010. EPA believes that the chemical-specific approach and FDA’s formulation-specific approach are equivalent from a risk management perspective, inasmuch as each would result in the same levels of residues from these chemical substances.

As part of the duplication, EPA changed the naming conventions (chemical nomenclature), as well as combining, as appropriate, chemical substances that appear in 21 CFR 178.1010 under two or more names under a single name. The Agency has attempted to identify each of the listed chemical substances using the Chemical Abstracts Service Registry Number (CAS No.). The CAS No. provides one of the most distinct and universally accepted means of identifying chemical substances. Generally, there will be only one CAS No. per listed chemical substance; however, it is possible that more than one CAS No. may be appropriate for some chemical substances. The lack of a CAS No. will not preclude EPA from including chemical substances in 40 CFR 180.940.

The lower-concentration limits specified in 21 CFR 178.1010 are not included in 40 CFR 180.940 because of the differences between FDA’s approach and EPA’s approach. Although EPA establishes tolerance exemptions for use in food-contact surface sanitizing solutions under FFDCA, all pesticide products must also meet the criteria for registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) before being offered for sale. EPA relies on conditions imposed through the FIFRA registration process to address safety and for antimicrobial-formulated products efficacy. Accordingly, the lower limits on concentrations of pesticide chemicals, that appear in 21 CFR 178.1010 will not appear in 40 CFR 180.940. Three types of food-contact surface sanitizing