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# A Look at the Food Handler Antiseptic OTC Rulemaking

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On December 7, 2018, the Food and Drug Administration (FDA) established a docket and requested data, information, and comments to "assist the Agency in assessing the safety and effectiveness of food handler antiseptic drug products (*i.e.*, antiseptic hand washes or rubs intended for use in food handling settings) for over-the-counter (OTC) human use." The request for information (RFI) "is part of FDA's ongoing evaluation of the safety and effectiveness of OTC drug products marketed in the United States on or before May 11, 1972." Products not on the market before May 1972 must undergo drug review rather than taking advantage of the OTC monograph. The comment period was reopened on April 24 and it closed on July 23.

FDA provided a list of questions in its RFI to direct comments. These questions covered:

- Definitions of food handler antiseptics (categories of workers who might use the products, settings in which used, limitations of use, types of products, and frequency of use);
- Active ingredients (eligibility of ingredients for consideration in the OTC monograph, ingredients currently in use, history of availability);
- Safety, including the risk of antimicrobial resistance caused by the products, the need for clinical studies on the products (showing reduced incidence of illness) and the potential for transfer of the products to food handled after use of the products; and
- Effectiveness of the products.

The American Cleaning Institute (ACI) provided comments addressing many of the specific questions raised by FDA in its RFI. Of particular interest, ACI indicated that because the use of the active ingredients will be "biocidal (not biostatic)" food handlers are unlikely to "be exposed to a theoretically selective environment of sub-cidal concentrations" and are thus unlikely to encounter risks of antimicrobial resistance. Further, because of the many factors that would have to be controlled for an effective clinical study, ACI argues that demonstrating the effectiveness of the sanitizers in reducing or eliminating bacteria of concern should be a sufficient demonstration of effectiveness. Finally, ACI argues that the quantity of active ingredient expected to transfer to food by use in a food handling facility is expected to be so low that there will not be a risk to consumers of the food.

The use of sanitizers has been recently addressed by FDA in the context of the Food Safety Modernization Act (FSMA). For example, in Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry, see our blog post here, FDA

states that there are times when hand sanitizers may not be used in lieu of soap and water.



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