



September 10, 2009

Dolana Blount
PURE Bioscience
Director of Regulatory Affairs
1725 Gillespie Way
El Cajon, CA 92020

RE: Sanitizers for surfaces and equipment in food processing facilities

Dear Ms. Blount:

This is in response to your September 2, 2009 e-mail in which you requested clarification of FDA jurisdiction in regards to the regulation of sanitizers used on surfaces and equipment in food processing facilities.

You are correct in noting that the authority to regulate the use of sanitizers on food equipment and utensils was transferred to the Environmental Protection Agency (EPA) by the 1996 Food Quality Protection Act (FQPA). EPA now has the sole authority to regulate sanitizers used on food equipment and utensils under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Title 21 of the Code of Federal Regulations (CFR), part 178.1010 has not been updated to reflect the change in authority that took place in 1996. References to sanitizers for equipment and utensils within 21 CFR 178.1010 are no longer applicable. References to 21 CFR 178.1010 in the document on the USDA website you cited, <http://www.fsis.usda.gov/oppde/larc/compounds/cbrpcriteria.html#Sanitizers>, should be updated to reflect the passage of the 1996 FQPA.

If you or any of your clients have further questions, please do not hesitate to contact us.

Sincerely,

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