Procter&Gamble

The Procter & Gamble Company Sharon Woods Technical Center 11530 Reed Hartman Highway, Cincinnati, Ohio 45241-2422

June 24, 1998

Docket Management Branch (HFA-305) Food and Drug Administration Room 1-23, 12420 Parklawn Drive Rockville, Maryland, 20857

0936 '96 JUN 26 P1:29

Re: Docket Number 97N-0451

Dear Sir/Madam,

This responds to the FDA's request for comments on its *Draft Guidance to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, issued on April 13, 1998. The Procter & Gamble Company is pleased to provide these comments for consideration in future revisions of the Guide.

Overall, we commend the FDA and USDA for assembling what promises to be an informative set of recommendations that will help reduce the risk of consumer exposure to foodborne pathogens. We especially laud the agencies for recognizing that practical measures must focus presently on risk reduction, not risk elimination, and that food safety is a shared responsibility for everyone from "farm-to-table". Further, we agree with the agencies' call for enhanced efforts to educate consumers on good produce handling techniques, including the thorough washing of all fruits and vegetables to be eaten raw.

We are, however, concerned that some specific recommendations in the guide are not consistent with current and historical registration policies within the Environmental Protection Agency, Office of Pollution Prevention, Antimicrobial Division. This federal authority has jurisdiction over the registration of safe and effective sanitizing chemicals for produce washing in (or near) the farmer's field and in the consumer's home. The EPA has, to date, not issued any efficacy standards for pathogen control; all current registrations for produce sanitizers are for control of spoilage organisms only, not for human pathogens. This policy has given rise to the practical distinction between "food quality" (spoilage control) and "food safety" (pathogen control) that this guide does not acknowledge. Given this, the guide may be making pathogen control recommendations for field and food packing facilities that are not in compliance with the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act under EPA jurisdiction. Therefore, it behooves the FDA and USDA to consult closely with the EPA Antimicrobials Division prior to finalizing its food safety guidelines.

Again, we hope these comments are useful to the agencies in future revisions of this important guide. If you have any questions regarding these comments, please do not hesitate to call me at (513)626-3636.

Best Regards, THE PROCTER & GAMBLE COMPANY

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William F. Holman, Associate Director Professional & Regulatory Services

cc: D.C. Winn, S.K. Puryear, B.N. Johnson



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