



CHEMICAL MANUFACTURERS ASSOCIATION

COURTNEY M. PRICE
VICE PRESIDENT
CHEMSTAR

June 29, 1998

Food and Drug Administration
Dockets Management Branch (HFAS-305)
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

1350 '98 JUN 30 11:15 H.K.P

RE: Comments on Draft Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables - Docket # 97N-0451

Dear Sir or Madam:

The Chlorine Dioxide Panel (Panel) of the Chemical Manufacturers Association (CMA) submits these comments on the draft "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" guidelines. The Panel is comprised of members representing Vulcan Chemicals, Vulcan Chemical Technologies, IDI/Englehard Corporation, Sterling Pulp Chemicals, Ashland Chemical Company and Elf Atochem.

It is widely recognized that microbial loads can be quite high on fresh fruits and vegetables due to exposure in the field, in transport and through handling and processing. The problem has been well defined within the guidelines and we concur that principles 1 through 8 in the guidance document are critical in reducing potential microbial contamination and the subsequent health risks.

While the Panel supports certain aspects of these guidelines, the following points must be made:

- Our largest concern with the proposed guidelines is the reference in footnote 7 to chlorine dioxide being unstable and explosive when concentrated. Without providing a better explanation of the conditions necessary for this compound to be unstable and explosive, this brief description would undoubtedly alarm and confuse potential users of chlorine dioxide in antimicrobial applications. A concentration of 10% is the lower limit of the explosivity of chlorine dioxide. Typical use concentrations of 1-5 ppm (0.0001-0.0005%) are much lower than the lower limit and are completely free from explosive hazard. *The Chlorine Dioxide Handbook*, published by the American Water Works Association, is an excellent source of information concerning chlorine dioxide and safe handling.

97N-0451



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- The use of antimicrobials to control pathogens in wash water and flume water should be actively recommended rather than merely suggested. While irrigation waters may play a role in microbial contamination, waters associated with processing fruits and vegetables (especially wash water, transport water and cooling waters) can be serious sources of contamination and cross-contamination. In many cases, these "early" waters are extensively recycled, and can thus concentrate microbial contamination and organic loads. High organic loads will serve to neutralize sanitizers added to these waters and as a result, these waters can potentially become an inoculum to the produce. In the case of flume, rinse and cooling waters used post inoculum, it is critical to use antimicrobial treatments that are safe, but also effective at low concentrations and against a broad spectrum of pathogens.
- Footnote 6 in the guidance document states that there are 3 major groups of chlorine compounds: liquid chlorine, hypochlorites and chlorine dioxide. The inclusion of chlorine dioxide within a list of chlorine compound types is not entirely accurate, since chlorine dioxide is not actually a "chlorinating compound". A more accurate listing of chlorine compounds would be, gaseous chlorine (Cl₂), liquid chlorine (sodium hypochlorite), and powdered chlorine (calcium hypochlorite). The principal chemical reaction of chlorine and other chlorinating compounds is electrophilic substitution, while that of chlorine dioxide is primarily a simple oxidation.
- In Footnote 7 of the guidelines, the statement is made that "Chlorine dioxide may prove to be useful for washing intact fruits and vegetables at a concentration not to exceed 5 ppm." Chlorine dioxide in process waters of fruits and vegetables has a long and highly successful history of use, especially in recirculating water systems with high organic load, such as flume and wash tanks. An expansion of this use, codified at 21 C.F.R. §173.300 (b)(2), is anticipated to be published in June 1998 and will permit the use of chlorine dioxide in water used to wash both cut and uncut fruits and vegetables at a concentration not to exceed 3 ppm.
- The following statement made in Footnote 7 of the guidelines needs clarification: "additional research is needed to determine its effectiveness against specific pathogens." The effectiveness of chlorine dioxide against specific pathogens is well documented. There is a significant volume of literature references and laboratory studies attesting to chlorine dioxide's potent and broad spectrum antimicrobial activity, including *Escherichia coli* O157:H7. For example, a summary of chlorine dioxide's abilities and its effectiveness against a variety of pathogens may be found in the draft *Alternative Disinfectants and Oxidants Guidance Manual*, prepared for the EPA Office of Groundwater and Drinking Water. In addition, there is ongoing

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research to document the effectiveness of chlorine dioxide against
Cryptosporidium parvum.

The Panel supports the development of guidelines to minimize microbial food safety hazards. Food safety is a critically important issue, and all available compounds and techniques that can reduce or eliminate foodborne pathogens should be enlisted, recommended and promoted. Within the rather small group of appropriate antimicrobial compounds, chlorine dioxide has proven to be an excellent and appropriate candidate due to its high activity at low concentrations, and its ability to perform in high organic loads.

The Panel thanks you for this opportunity to provide comments and would be happy to provide supporting documentation or additional technical information upon your request. If you have any questions or comments, please call Ms. Marian Stanley of my staff. Ms. Stanley is the Manager of the Chlorine Dioxide Panel and can be reached at (703) 741-5623.

Sincerely yours,

A handwritten signature in black ink that reads "Courtney M. Price". The signature is written in a cursive style with a large, prominent initial "C".

Courtney M. Price
Vice President, CHEMSTAR

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Message or comment ...

Dear Ms. Harris,

The Chemical Manufacturers Association submitted the attached comments to your office by Federal Express on Friday, June 26. Unfortunately my office was not aware of your new address and they were not delivered.

I spoke with Mr. Lyle Jaffey this morning and he said that it would be alright to submit the comments today. I will have the original copy delivered by messenger before close of business today.

If you have any questions, please call Leyla Lange at (703) 741-5625.

Regards,

Beth Walkos
Administrative Assistant, CHEMSTAR

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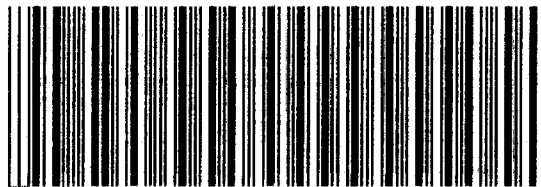
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