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January 3, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 97N-0511 (Fresh Citrus Juice)

Dear Sir/Madam:

I am writing as a member of the U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) regarding the December 8 and 9 meetings which covered the topic of "fresh squeezed citrus juice." After the two days of presentations and deliberations, the NACMCF answered a list of questions posed by FDA. The answers provided by Committee members addressed many of the troubling issues regarding past recalls and illnesses related to fresh squeezed orange juice. At the close of the two-day session, it was requested that members with additional comments submit them in writing. At the meeting, I expressed concern that there were additional items, beyond those discussed, which FDA should consider in regard to the safety of fresh squeezed orange juice. I am writing now to express my views regarding some of those additional items.

Background

While I do not speak for the Committee as a whole, I would like to respond, for the record, to some of the comments made during the presentations and to submit further thoughts on the matter of appropriate sanitary measures for citrus juices. First, several commentators noted that "pasteurization is not the answer." It is my opinion that had processors of juice been pasteurizing, the previous outbreaks of foodborne illness linked to consumption of unpasteurized juices would not have happened. To me, this is very clear. I trust we do not have to recap over 100 years of success of pasteurization as an adequate public health protective measure. Let me reiterate, however, that I do not disagree with the opinions expressed by the NACMCF or with the recommendations that were made. My only Docket

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disagreement is with opinions expressed by some presenters at the meeting relative to their view of pasteurization.

In order to set the stage for making the suggestions below, I would like to review what, from my view, were four of the more relevant points discussed during the meeting. First, several of the questions FDA asked the Committee to address dealt with potential for internalization of human pathogens within oranges and the potential health risk if this event did occur. While the question is still open as to whether internalization is likely to occur in a commercial setting, the NACMCF did not feel that this is a highly likely event or that this potential contamination source would contribute to a significant public health risk. At this time, I do not disagree with this position. It should be cautioned, however, that results of ongoing investigations may invalidate this conclusion and, thus, some reservation must be associated with this assumption. As the question of internalization of human pathogens within citrus fruit is still somewhat open, I would encourage the Agency and the industry to continue work in this area.

Another of the more relevant bits of information was the summation of the results of microbiological testing compiled by four fresh juice companies and presented on their behalf by Dr. Jur Strobos. We were informed that among these four processors over 17,500 microbiological tests have been run on finished product for the presence of enteric pathogens. No pathogens were reportedly found in these samples. While this is impressive, it should be noted that there were questions expressed by the Committee regarding the methodology used in these tests. As we have recently seen, methodology used in testing for pathogens in orange juice is of a critical nature when determining the validity of results. It was obvious from the presentations that methodology had varied among processors and had changed throughout the development of the data set. While I feel that FDA needs to further elucidate the methods used in development of these data and should also determine results of other microbial testing, (e.g., *E. coli* testing when conducted), the test results reported are compelling and should not be ignored.

The Committee was also informed by Dr. Steven Pao from the Florida Department of Citrus of the efficiency of modern juice extraction equipment and the fact that juice contact with the outside of the fruit is minimal with these systems. Dr. Pao noted that when juice was extracted from fruit contaminated on its surface with approximately 10^5 organisms, slightly more than 10^3 of the test organisms were recovered from the juice. In other words, almost 99% of contaminants were not transferred to the juice during the extraction process. The fact that even a small percentage of surface contaminants is transmitted to the final product points to the critical nature of an effective culling of highly contaminated fruit and a successful surface treatment to remove or inactivate microorganisms.

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A fourth, and possibly the most significant, part of the discussions addressed probable causes for previous problems with fresh squeezed orange juice. Even though the question of internalization of organisms is still open, information presented at the meeting did not indicate that prior problems have been caused by internalization of pathogens within fruit. Although not conclusive, several presenters noted that evidence surrounding recent outbreaks of foodborne illness and findings of contamination with human pathogens in fresh squeezed juice strongly suggest that the contamination resulted from inappropriate handling of juice after expression. Thus, it is apparent that added focus is needed for the handling of juices that do not receive a microbial kill step.

Discussion

As I noted a few times during the meeting, the 5-log reduction stated as a goal in the proposed rule is designed to meet a specific level of protection to consumers and should not be viewed as a goal unto itself. As I remember the NACMCF discussions that resulted in this recommendation (5 log reduction), it is designed to produce a juice that presents a reasonable certainty of no harm. The 5-log reduction is not an objective that should be viewed as a stand-alone criterion. In reading my remarks below, this fact should be kept in mind.

The question above regarding appropriate methodology for recovery and identification of enteric pathogens in citrus juice is a very relevant part of what I believe is a key concern. This concern relates to the scientific rigor with which the safety of fresh juices is to be assured and how a processor of fresh juice validates procedures to achieve the public health objective stated in the preamble to the proposed rule on HACCP for juices. The 17,500 data points noted earlier were developed on juices that were apparently produced by oranges handled and processed in very specific ways. What was offered to the Committee was that juices made by these four companies were processed under conditions similar to those prescribed within the Florida guidelines. What the Committee recommended as a result of these discussions was that a processor of fresh squeezed orange juice should use sound "wholesome" fruit (choice grade?) with no "drops" permitted. This, presumably, would reduce potential for internalized pathogens being introduced into orange juice. It is also reasonable to assume that it is easier to decontaminate the surface of fruit of this quality. The NACMCF further recommended that orange juice sold without application of a kill step just prior to packaging not be expressed in one location and transported to a second for final packaging. In other words, orange handling, washing, sorting and juice extraction should all be done in the same location and in close proximity from a time standpoint to final packaging. Use of sanitizing rinses and high-pressure washes (without immersion) as encoded in the "Florida Model" were also addressed in the recommendations given by many of the members of the NACMCF.

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Suggestions for consideration

As noted above, my concern is the scientific rigor with which the targeted microbial reduction must be proven. It is my understanding that the approach outlined above assumes a microbial reduction credit for washing of fruit in meeting the 5-log criterion. In addition, further credit is

also assumed on the basis that the method of juice extraction used in commercial operations results in the transfer of only a very small percentage of surface contaminants to the juice during extraction.

In conducting testing to validate process delivery, I think it is important that testing be conducted under commercial conditions in order to confirm the validity of assumptions derived from laboratory testing. For example, a clean system with fresh sanitizer may be very effective at reducing surface contamination, but does the system maintain its efficiency after a few hours of running? Is the reported lack of transfer of contaminants during extraction sustained throughout the production day? Also, microorganisms that occur naturally may form attachments that make them difficult to remove. Is this important and, if so, has this been considered?

In judging adequacy of claimed microbial reductions for fresh orange juice, FDA may wish to consider an approach similar to that which has proven very successful for low-acid canned foods and for acidified foods. A system that relies on the recommendations of a process authority to attest to the adequacy of the processes to be employed has been used successfully in other areas of the food industry. I feel that it is essential that processes not involving a defined kill step in the orange juice should be rigorously reviewed. A responsible individual (e.g., a process authority) should provide assurances (available to the Agency) that if certain defined procedures are properly followed, 5-log reduction will be achieved for juices to be marketed as fresh. Of course, within a HACCP system, records would be available to verify that the appropriate procedures are being followed.

In addition, the NACMCF recommended microbiological testing of finished orange juice. On the basis that there are few other verification steps which can be utilized for this process, this appears to be sound advice. On the other hand, if juice is provided a validated kill step just prior to packaging, (e.g., pasteurized) the most effective verification of the effectiveness of the applied kill step will come from data developed for process design and records of proper delivery. In this case, microbiological testing of the processed juice should not be necessary. However, given the lack of other assurances of achieving a 5-log reduction in fresh juices, it would appear necessary to do some finished product testing. Again, this need not be lot-by-lot acceptance testing but some ongoing monitoring to check for effectiveness of the processing steps that are taken. My earlier caution regarding appropriate methodology would apply here as well.

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In summary, it continues to be my privilege to be a member of the NACMCF. I continue to support its good work and submit these comments as a member of the Committee.

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink that reads "Dane Bernard". The signature is fluid and cursive, with the first name "Dane" and last name "Bernard" clearly legible.

Dane T. Bernard

Member

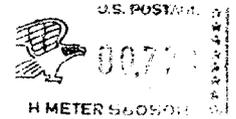
U.S. National Advisory Committee on Microbiological Criteria for Foods

CC: Ms Janice Oliver FDA
Dr. Rhona Applebaum NFPA
Dr. Karen Hulebak FSIS



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