COMMENTS ON NACMCF'S RAW ORANGE JUICE MEETINGS

January 24, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 97N-0511- Juice HACCP,

Safe Tables Our Priority is a nonprofit, grassroots organization consisting of victims of foodborne illness, family, friends and concerned individuals who recognize the threat pathogens pose in the U.S. food supply. We count among our members victims of outbreaks from *E. coli* O157:H7 contaminated apple juice and *Salmonella* contaminated orange juice. S.T.O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness. We have previously submitted comments on this topic for:

- the February 3, 1997 docket on the topic of juice safety;
- the September 12, 1997 docket for FDA's Notice of Intent on Juice Safety;
- the May 26, 1998 docket on FDA's Proposed Rule on Juice Labeling;
- the August 7, 1998 docket on FDA's Proposed Rule for Juice HACCP;
- the January 19, 1999 docket on Citrus Juice Scientific Technical Meetings.

Today, we are writing to comment on issues raised prior to and at the December 8-9 meetings of the National Advisory Committee on the Microbial Criteria for Food (NACMCF) on the subject of the relative safety of raw orange juice. S.T.O.P. strongly supports FDA's efforts to improve juice safety, and we appreciate this opportunity to provide additional comments on the subject.

After careful study and consideration, and in the wake of 13 foodborne illness outbreaks and recalls from raw juice in the last 10 years alone, we urge FDA to require mandatory pasteurization of all juice as part of a company's HACCP plan until alternative processes are proven to be as safe and as reliable.

The United States experienced its largest-ever foodborne illness outbreak from raw juice in June and July, 1999. Nearly 500 people became ill and one person is known to have died from Salmonella contaminated orange juice produced and distributed to nine states by Sun Orchard of Tempe, Arizona. Sun Orchard claimed that the juice was produced using a multiple step 5-log reduction system in accordance with FDA's proposed juice safety regulations; the juice was not heat pasteurized. Contaminated juice was recalled at that time. Again in November, Sun Orchard had to recall thousands of gallons of orange juice from eight states for Salmonella contamination. Also, during the fall of 1999, seventeen people were sickened in Oklahoma from raw apple juice, with three children suffering from kidney failure.

The combination of outbreaks and recalls in 1999 demonstrate that consumers are not adequately protected by FDA's proposed juice safety regulations. FDA's proposed regulations have failed to address:

- recurring factors in outbreaks such as the use of drop fruit
- the role small processors have played in outbreaks
- the inability of retail/restaurants to meet FDA's performance standards
- measuring contamination levels on incoming fruit
- HACCP back to the orchard
- variation in harvest and juice processes around the country

and other factors we will mention below. In contrast with FDA's proposed rules, heat pasteurization has a century-long, proven track record of effectiveness in protecting the public health. The time has come to require all juice to be pasteurized until alternative technologies are proven to be as effective.

The balance of our comments today are structured as follows:

S.T.O.P. is pleased that the NACMCF finally concluded that the place to begin measuring microbial reduction interventions is after a culling/washing step that removes visibly damaged fruit and visible dirt. S.T.O.P. has repeatedly supported this approach and was greatly relieved that NACMCF could see that this was a critical necessity as well.

I. General Concerns Re Raw Citrus Juice Production

In U.S. and foreign outbreaks of raw and underpasteurized juices, a consistent trend has emerged. *E. coli* O157:H7 and *Cryptosporidium* have been repeatedly associated with raw apple juice/cider. *Salmonella* has been repeatedly associated with raw orange juice.

At the December 1999 NACMCF meeting, Dr. Mohamed Ismail of the Florida Department of Citrus argued that lack of processing sanitation was the key factor in

all outbreaks and therefore that raw juice could be made safely in conjunction with a HACCP plan. Yet, if processing plant sanitation problems were the sole factors, one would expect to see the resulting microbial contamination would be more varied per type of fruit. Each episode of contamination would then be a function of the many different plants and processing techniques around the country. Instead, empirically, we see oranges juiced in Florida, Arizona (In Sun Orchard's, case, Mexico?), California and even Australia producing Salmonella contaminated orange juice, and apples juiced in California, Washington, Maine, Michigan, New York, Connecticut and even Canada producing *E. coli* O157:H7 and *Cryptosporidium* contaminated apple juice.

S.T.O.P. believes that the consistency of the recurrence of specific pathogens in outbreaks of specific types of raw juice strongly suggests that growing, harvesting and juice processing practices specific to each industry select for these pathogens. In the case of apple juice, the use of drop apples has been consistently implicated. In the case of orange juice, potential factors that S.T.O.P. believes set the raw orange juice industry apart and warrant further investigation are:

1. the temperature in groves at the time of harvest (1);
2. the prevalence and use of poultry-feces derived fertilizers;
3. waxing of fruit; and
4. he use of mechanical harvesters.

S.T.O.P. believes that FDA needs to understand why *Salmonella* is repeatedly associated with raw orange juice outbreaks in the U.S. and other countries in order to pinpoint critical control points for a HACCP plan.

The temperature differential of the fruit between harvest and processing (number one above) was raised at the NACMCF meeting and we will review it below. However, the NACMCF did not discuss in any detail the subsequent three points. S.T.O.P. strongly urges FDA to identify the impact that the use of poultry feces fertilizer has on the pathogenic load carried on incoming fruit to a juicing process. FDA also needs to investigate the impact that the waxing process could have on the growth of *Salmonella*. The application of fungicide prior to waxing, acknowledged to be a fairly common industry practice, could create an uncompetitive microbial environment favoring the growth of *Salmonella* beneath the wax. We also urge FDA to investigate whether the use of mechanical harvesters and the resulting microscopic damage could create minute crevices on choice fruit which would escape brushing and sanitizing later in the process, thereby reducing the effectiveness of brushing/sanitizing as a reduction method.

We are concerned that combinations of errors in assumptions would undermine the NACMCF's understanding of the industry's ability to effectively deliver a cumulative 5-log reduction (see Appendix A for more data). Without proper data, the committee's ability to develop scientifically sound recommendations on FDA's behalf should be questioned.

II. Concerns About the NACMCF Meetings, 12/8-9, 1999

A. No Presentation of Overall Outbreak Information

In previous comments, S.T.O.P. has repeatedly asked FDA to create accurate tables of outbreaks and present them at the beginning of every relevant meeting and publish them in every proposed rule. Every opportunity that CFSAN has to educate both NACMCF and industry about the prevalence of outbreaks and their potential causes is an opportunity to gain greater insight into the breadth and depth of the problem. In addition, attendance both on the committee and in the audience fluctuates throughout the years, with new attendees not having received the most basic background. Without concrete evidence on the breakdowns of SSOPs and HACCP which have been linked to outbreaks, NACMCF cannot give fully informed advice to CFSAN. When CFSAN fails to present this information at the beginning of meetings, it leads to different factions presenting conflicting, inaccurate, and incomplete data. S.T.O.P. offered an example chart to FDA in its Juice HACCP comments dated August 7, 1998, which is updated and included here as Appendix B.

On day two of the December, 1999 NACMCF meeting, at consumers' request, CFSAN did hand to the committee a brief slide of outbreak data. Unfortunately, this slide did not reflect all of the outbreaks and recalls described in CFSAN's own Proposed Regulations for Juice HACCP and Labeling. The result was that at the end of the meeting, the committee had received three lists of outbreaks and/or recalls, none of which were identical, and it was unclear whether any other than S.T.O.P.'s addressed a point critical for NACMCF and the industry: what is the suspected cause of each outbreak?

We understand that FDA had not yet finalized its report on the Sun Orchard outbreak and that at the time of the meeting, it was still investigating the latest recall; however, we strongly believe that preliminary information in this area should have been made available to the NACMCF.

Once again, we believe this data needs to be presented, not simply handed out, and a summary of the data should be given by a **neutral** party, preferably a member of a federal agency who is familiar with the epidemiological investigations and their final results. At the December 8-9 NACMCF meetings, Dr. Mickey Parrish of the University of Florida was asked to give a summary of the cause of the 1995 Disneyworld, raw orange juice outbreak. Earlier in the meetings, Dr. Parrish had sided with the consortium of juice producers supporting 5-log reduction HACCP. His response identified contamination of the Disneyland outbreak as originating exclusively at the plant.

However, in comments made at the December 16, 1996 FDA juice meetings, Dr. Patricia Griffin of the Centers for Disease Control indicated multiple potential sources of contamination, at least one of which was pertinent to the issue of incoming, fruit-borne contamination:

"The oranges came from many groves, but a major grove used surface water for irrigation. The oranges were often knocked from the trees onto the ground, and later, cultures of both soil and the surfaces of oranges yielded salmonella.

The plant investigation showed that the plant used a phosphoric acid rinse to clean the oranges. Salmonella strains were isolated from a toad and a frog outside the plant, and animal droppings were found inside the plant.

This environmental work was done by Mickey Parrish of the University of Florida."

Dr. Griffin's additional data about dropped fruit and contaminated oranges was not mentioned at the 1999 meetings. Chicken manure was reportedly used on fields nearby as well(2).

In summary, for NACMCF to make accurate recommendations, it must have **all** the data. We believe that NACMCF was erroneously led to believe at the December, 1999 meeting that fruit-borne contamination has not played a significant role in orange juice outbreaks.

B. Size of the Industry Continues to Be Underestimated

In previous comments, including S.T.O.P.'s 5/26/98 on juice labeling and the 1/19/99 comments on citrus juice reduction technologies and HACCP, S.T.O.P. has repeatedly challenged FDA's calculation that only 2% of the juice market is raw. We provided information that this percentage might be significantly higher based on additional market segments that have been ignored and sales of juicing machines, which indicate that many more consumers were in fact consuming raw juice than recognized by FDA. We are especially concerned because many of these producers are companies who fall into retail or small producer categories (<10,000 gallons) that are not covered by FDA's planned regulations. We believe that the NACMCF should have accurate figures about the national consumer rate of consumption of raw juices. Understanding the volume of juice produced is critical to understanding the likelihood of a threat to public health outbreak, one of the questions under consideration for the meeting.

C. Breadth of Industry Representatives/Experiences Not Presented

At the meetings, CFSAN had a handful of knowledgeable presenters familiar with advanced, larger scale, raw juice manufacturing. Multiple speakers brought insight into some of the better raw production practices of larger scale Florida juice production, and a single speaker had familiarity with Sunkist production and some more general growing practices in the San Joaquin and Sacramento Valleys of California.

Particularly in the absence of data on outbreaks, S.T.O.P. was disturbed that no industry representatives were familiar with or presented data on the less common and smaller production practices. Practices in climates as diverse as Texas and the Coachella Valley of CA were notably underrepresented. NACMCF members could easily get the impression that the Florida/California consortium's practices represented the bulk of the raw juice industry rather than merely what is optimal today. As a result, there was limited, if any discussion, about the variations amongst pre-processing practices in the production of raw juices.

Even when the following practices were brought up at the meeting, they were dismissed by industry presenters as unusual and discouraged and therefore not necessary to consider:

- Orange groves with no fencing to keep out cattle
- Cattle grazing in orange groves
- Growers using chicken manure or raw, uncomposted manure as fertilizer
- No overnight holding on some fruit prior to packing or processing
- No cold storage step for some fruit prior to entering a processing facility

Any of these steps could lead to increased pathogen loads on incoming fruit or contribute to internalization; yet, the potential was largely ignored.

Lastly, left completely unmentioned was information that Dr. Martha Roberts of the Florida Department of Agriculture and Consumer Services presented at the 11/12/98, FDA Technical Workshop held at the Citrus Research and Education Center, University of Florida, in Lake Alfred, Florida. Inspections by the Florida State Division of Fruit and Vegetable and USDA's Agricultural Marketing Service conducted between 1996 and 1998 found 4% of raw juice samples and 5% of firms had contamination. Furthermore, this data excluded producers that are squeezing less than 30,000 boxes of fruit, gift fruit shippers, retail processors and roadside stands, which went uninspected. It strongly reinforces that contamination in raw citrus juice is not an unusual, insignificant, or unlikely problem.

S.T.O.P. would argue that it may be exactly these "less usual" practices that are leading to citrus juice foodborne illness outbreaks, and that CFSAN and NACMCF need to understand these risks prior to finalizing the quantity of log kill. We believe an open, honest discussion of these "alternative" practices would give the committee a much more accurate picture of the potential nature of contamination and the challenge of determining how to effectively calculate a cumulative reduction, where to start and the magnitude of reduction that is necessary to render juice safe.

D. Lack of Juice Bar Industry Participation

S.T.O.P. has encouraged FDA to invite multiple juice bar chains to these meetings, along with representatives of grocery store chains. It is unfortunate that the juice bar industry and grocery store chains choose not to participate more in the public process. They represent a unique aspect of the raw juice industry. Please review attached comments directed to the City of Saratoga on the subject of the lack of safety in juice bar juice production and the need for more stringent requirements (Appendix C).

E. Test Results Might Be Less Valid Than Presented

S.T.O.P. is very concerned with data presented at the NACMCF meeting from CFSAN labs and from industry testing and feels that more complete and accurate data is needed before conclusions can be drawn from this data. First, in most of the laboratory innoculated fruit tests presented by both CFSAN and industry, there was little discussion of biofilms, and the difference between laboratory grown bacteria and those occurring in nature. Organisms forming biofilms are often found to be harder to kill than laboratory grown organisms. In alfalfa sprouts, the formation of biofilms inside a cracked seed is considered to create a highly intractable contamination situation. Tests showing how laboratory innoculated fruit can achieve significant reductions should be compared with tests where the fruit is innoculated on the tree, with organisms grown and harvested non laboratory conditions.

Second, the Florida/California consortium presented that they had run 1.7 billion pieces of fruit and tested 17,000 batches and that they had never had a positive for a pathogen, which appeared to impress members of the NACMCF. Yet, testing protocols varied widely among these four producers, and none of them used the BAM test with Universal Pre-enrichment broth as now recommended by FDA. In addition, the two California companies were not even testing for generic E. coli, and the two Florida companies had had 20 positive tests for generic organisms.

We believe that the time has come for FDA to conduct real incoming citrus fruit and end-product citrus juice testing. To start, FDA could enroll its pilot HACCP plants, including the smaller Fresh Samantha and a major California juice bar, in a mandatory BAM-with-preenrichment testing program conducted with qualified, uniformly applied, scientific testing, supported by government, not industry, so that the test results could be compared.

Identifying small quantities of *E. coli* O157:H7 and *Salmonella* is notoriously difficult to do. Nevertheless, FDA must ensure that testing methods presented to NACMCF will, in fact, find the organisms, rather than allowing dubious test results to be touted as examples of the success of HACCP programs.

III. Concerns About the NACMCF's Conclusions

We disagree with NACMCF's conclusion on two points, particularly the role of internalization as a threat to public health, and the potential for overreliance on sound fruit as a preliminary step prior to measuring the 5-log reduction.

A. Concerns About Internalization Conclusions

FDA has shown that internalization is theoretically possible. We believe that circumstances exist in industry which may render this theoretical probability quite possible, though we believe FDA did not demonstrate this to NACMCF. S.T.O.P. is very concerned that FDA not conclude, because of NACMCF's lack of response to question 1c,

"If internalization of pathogens into citrus juice is theoretically possible, is such internalization likely to result in a public health risk?

that NACMCF believes internalization represents no public health threat. Rather, at the meeting it appeared that NACMCF is unconvinced that internalization can occur outside of a laboratory and needs more data.

Two words in this question made this question difficult to answer. They were "theoretically" and "likely."

In particular, without the data that S.T.O.P. has indicated needed to be presented at the meeting, including:

- Accurate size of the market

- Accurate descriptions of the number and causes of all citrus outbreaks and recalls
- Accurate information about variations in growth-to-juice practices
- Accurate test results of contamination in juices

we do not believe that the NACMCF members could draw a conclusion about the "likelihood" of internalization.

Repeatedly at the meeting, industry members downplayed the less usual circumstances that would exacerbate internalization under non theoretical circumstances. Industry repeatedly indicated that fruit would always be reduced in temperature either through overnight holding or through cold storage prior to juicing, which would eliminate the temperature gradient that enhances internalization. Yet this step has never been required by CFSAN regulations or by SSOPs. Data on practices in warmer climates such as that of the Coachella Valley and Texas was very limited and gathered hurriedly.

Industry also downplayed the use of dunk tanks, which could contribute to internalization, as a relatively insignificant portion of the industry. Yet, at the meeting, Dr. Arpaia indicated that dunk tanks were employed by 30% of the California producers. She also indicated that some of these producers use 200 ppm chlorine at a pH of between 8 to 10 in the water and that the water was changed only weekly. Even NACMCF meeting members indicated this was not sufficient to be considered detrimental to bacteria. Indeed, water such as this could contribute not only to internalization of pathogens in hot fruit that ends up cooling in the dunk water but to cross-contamination on external surfaces of fruit. Worse still, these steps may occur prior to the fruit even arriving at the juice processing plant where HACCP would begin and thus be outside the regulatory scope of the FDA's Juice HACCP regulation.

It takes very few pathogens to create lifethreatening illness. Under circumstances where an organism enters a plant and becomes entrenched on inadequately sanitized equipment, in water or in a batch of juice, the risk that the organism will spread is significant. Thus, any contamination in the system does represent a significant pubic health threat. Information presented to the committee indicated that the only viable killstep solution for orange juice at this time is heat pasteurization(3).

B. Concerns About Sound Fruit Conclusions

At the end of the meetings, NACMCF members generally concluded that the measurement of a pathogen reduction standard would need to begin with what was referred to as "sound" fruit, i.e. after culling and a basic washing at the site where the juice was to be processed. While S.T.O.P. applauds this conclusion as the earliest possible point of beginning any sensible reduction, we have three concerns.

First, the microbial load prior to reduction steps must be less than the quantity of reduction in order to render a food safe. If a 5-log reduction strategy is employed, the incoming load must be less than 5 logs. This is the same safety strategy employed in milk. The incoming milk must be at a certain "clean" level even though it's going to be pasteurized. While culling and a basic washing will have a positive effect on the cleanliness of incoming fruit to be juiced, it still must be verified that the incoming microbial load won't overwhelm the reduction strategy.

Second, culling, while removing overtly damaged fruit which might be inherently more susceptible to contamination, is not a good screen for microscopic microbial contamination(4).

Third, because it is subjective, culling is not consistently applied either from person to person, company to company or state to state. Processors using blacklight are more advanced than those not using blacklight as they may be able to identify contaminants on the surface of a fruit that are not visible in normal light. A first cull at either a packing house or a juice processors separates fruit into three grades: processed, choice and first. Though it was indicated that the majority of raw orange juice comes from choice grade fruit, there are no rules that prevent the use of processed fruit in raw orange juice.

Thus, while FDA may choose, as a result of NACMCF's recommendations, to require that processors use sound fruit, it is imperative the FDA tightly define it.

S.T.O.P. would remind FDA that improper culling was considered to be a contributing factor to the Odwalla apple juice outbreak. S.T.O.P. would argue that, in its final rule, FDA must create its own mandatory, common, minimum standard for culling to produce juice and not rely on outdated definitions. The use of technologies such as blacklight should be mandatory if FDA really hopes to do create a standard that all companies could use.

S.T.O.P. would also argue that as long as production of raw or "minimally processed" juice is allowed, a higher fruit quality standard needs to apply. Choice grade fruit suffers from more dimples and blemishes than first grade fruit, and therefore offers safe havens for pathogens from many reduction techniques preferred in minimal processing, such as brushing and sanitizing(5). If FDA continues to support cumulative reduction and minimal processing for raw juices, S.T.O.P. believes that producers should start with top quality fruit, i.e. first grade only, in order to ensure the minimum likelihood of microscopic fruit-borne contamination coming into the plant.

IV. Concerns About Issues Not Addressed

A. Data Supports the Need for More Than 5-Logs Reduction Standard

At the NACMCF meeting, S.T.O.P. asked the NACMCF to review its previous conclusion that a 5-log reduction was sufficient to render juice safe. We do not believe that NACMCF was given sufficient time to review this data and believe that a careful review of the chain of potential contamination is warranted. Any one of the several points we have raised (see Appendix A) is sufficient to indicate that the NACMCF could be off by at least a log.

B. New Data Supporting the Need for More Than 5-Logs Reduction Standard

At the December, 1999 NACMCF meeting, additional data was presented by Drs. Ismail and Arpaia that supports S.T.O.P.'s concerns that incoming pathogen loads may be higher than NACMCF's original supposition of 10+1 cfu/g(6) , thereby

rendering a 5-log reduction inadequate and ineffective in producing juice safe enough for public consumption. It was also pointed out that after the point of contamination, there may be ample opportunities for organisms to grow. Practices exacerbating the potential for initial contamination include cattle allowed to graze in orange groves and the application of raw, uncomposted manure, including that of poultry. Warm temperature conditions both outside and inside the plant would encourage growth and the potential for internalization once the oranges are placed in cooler water. Dunk tanks that are underchlorinated at the wrong pH would encourage the spread of organisms as would waxing of oranges at lower temperatures and pH's. In general, what industry attendees would have described as "atypical" growth, harvest and production practices heighten the probability of pathogenic contamination in a raw juice, and very few of them fall under the in-plant HACCP proposal FDA has promoted.

C. Juice Bars and Restaurants

Even if FDA simply accepts the NACMCF conclusions that:

> 5-log is sufficient;
> the measurement of a 5-log reduction should occur at a single site
> the measurement should begin after onsite culling and washing,

the NACMCF conclusions are startling for what they indicate about current raw juice production at retail.

S.T.O.P. has repeatedly asked FDA to mandate warning labels at retail as long as raw juices are produced without pathogen interventions and to move toward safer production under retail settings. This month, the state of Washington introduced new labeling requirements required at retail to identify unpasteurized juices sold by the glass in that state (Appendix D).

Information presented at the combined FDA Technical Scientific Workshops held in Irvine, CA and Lake Alfred, FL in November, 1998 has indicated that to obtain a 5-log reduction in a citrus juice under a multiple step, reduction method without heat pasteurization, the fruit must be brushed and heavily sanitized or heat sterilized, and a specific type of juicing equipment must be used, one which punctures a hole in the fruit rather than slices it in half. The 12/99 NACMCF conclusion was that after the fruit arrived at the production site and it received a minimal culling and washing there, then the combination of steps (brushing, sanitizing, puncture) would generally need to happen under reasonably tight time constraints at the same site. NACMCF came to this conclusion because of the concern that separating steps by significant distances or amounts of time would allow organisms to grow back from their reduced quantities.

To the best of S.T.O.P.'s knowledge, there is not a single retail facility in the United States presently minimally processing juice on site with sufficient steps to meet the NACMCF's definition of "sound fruit + 5-log reduction." We believe that few, if any, retail establishments perform a cull and minimal wash upon receipt of fruit, rather accepting fruit that has been shipped to them from a packing house. Even if they do cull and wash first, we do not believe that they follow the NACMCF advised wash-cull with a significant, **on site** brushing and sanitization. Essentially, this NACMCF conclusion exposes that virtually all U.S. retail establishments juicing on site are

producing juice that has not been 5-log reduced*.* Until FDA can document that retail establishments meet NACMCF's "sound fruit + 5 log reduction," we ask again that FDA mandate warning labels on all raw juices served at retail.

D. Start of 5-Log Reduction in Citrus Relevant to Other Juices

S.T.O.P. urges FDA/CFSAN to recognize that NACMCF's conclusion that the start of the measurement of a 5-log reduction should begin after a culling and washing of citrus fruit should be applied across **all** fruit as a minimum standard. FDA still has not produced guidelines for other juice producers, such as cider producers, with regards to where the 5-log measurement should begin. S.T.O.P. urges FDA to immediately publish that information, along with the latest information on the BAM/Enrichment testing and new *E. coli* testing methods used by USDA, so that all juice industries can begin implementing these procedures. This information is urgently needed to set standards that protect the public's health.

E. Use of Contaminated Water in Fruit/Juice Production

Poor water quality in the production of fruit or juice from fruit is a very real threat to the public's health. The potential for contaminated irrigation water, the use of contaminated water in mixing pesticides, and contamination in the rinsing, washing, cooling, and other functions of raw juice production have been implicated in past outbreaks as potential factors in contaminated juice(7). Even now, the state of California is presently setting standards for the application of untreated human wastewater to orchard crops.(see S.T.O.P. public comments to the State of California in Appendix E). S.T.O.P. expects FDA to mandate minimum water quality standards and water quality testing as a part of its HACCP recommendations in order to ensure that fruit and juice are protected from water- and fluid-borne contamination.

V. Concerns About Industry Representations About Consumer Preferences

In its call for public comments, FDA stated that, "The agency is aware that same consumers prefer to consume raw (i.e., unprocessed) juice." The agency then goes on to request from these consumers how much they are willing to pay for a gallon of raw juice.

S.T.O.P. believes that both FDA and industry have done an inadequate job of informing the public of the life threatening risks that consumers may take in consuming raw juices. Indeed, in past public comments, we have presented examples of industry publicizing disinformation about the relative safety of bulk produced, raw juices and encouraging consumers to drink raw beverages because of their supposed healthful properties.

In Appendices C and F, we include descriptions of health promotion by Jamba Juice of San Francisco, CA. Jamba Juice's 1999 marketing materials promote its beverages as alternatives to fast food, e.g. "a healthy, portable meal," proclaiming that they "make healthy eating easy, great tasting and fun." At the time of its outbreak, Odwalla, based out of Half Moon Bay, CA was using the slogan, "Drink it and thrive."

Another example of this consistent, national marketing was shown in a presentation at the December, 1999 NACMCF meeting delivered by Laura Zinn, the owner of a small juice company from Atlanta, GA. Zinn describes that they opened their raw juice company "because we knew firsthand the health benefits of fresh juice." She indicates that the destruction of enzymes through heating ruins their healthful properties, without citing evidence of how the body can employ these juice delivered enzymes through the intestines. She goes on to say, "I have stories of hope and recovery. There are individuals with cancer, AIDS, ovarian cysts and other maladies who choose to use fresh juice to boost their immune systems and improve their health."

For families whose at-risk loved ones have suffered the ravages of foodborne illness brought on by raw juice, this statement is of the gravest concern, and it is evidence of how uninformed the American public still is after three long years of education on the part of FDA to ensure that at-risk individuals are informed of the life threatening consequences. We believe that FDA must recognize that it has lost the battle against raw juice industry marketing, and it must take responsibility for protecting at-risk individuals who persist in potentially life threatening behavior because they are uninformed.

Therefore, if FDA asks consumers that prefer raw juice how much they are willing to pay for a gallon of raw juice, S.T.O.P. advises that FDA also request the price that same consumer would put on his/her own life and the lives of his/her children or parents for the purposes of economic analysis. If the cost of a gallon of raw juice is $3.50, but a consumer pays with his life, then the cost the consumer was willing to pay has really been $3.50 plus a life.

VI. Toward A Final FDA Juice HACCP Rule

S.T.O.P. has significant concerns that FDA/CFSAN and the NACMCF do not have enough data on industry practices and causes of citrus juice outbreaks to create a sound HACCP which does not include heat pasteurization. We therefore urge FDA to require mandatory pasteurization until such time as other intervention technologies are available.

S.T.O.P. maintains that the contamination of fruit is most frequently occurring outside the realm of the plant. Therefore, even the best HACCP plan that takes into account only the critical control points beginning upon receipt of fruit at the facility cannot be complete. FDA's proposed regulation did not even mandate testing of incoming fruit for pathogens. Under the proposed system, the processor need not know any circumstances pertaining to the fruit prior to its arrival at the plant, even though the condition of the fruit and whether it was dropped on the ground has been heavily and frequently implicated in outbreaks (8). For the many reasons above, including,

- Application of irrigation water
- Application of fertilizer
- Application of pesticides
- Harvesting practices such as the use of drop apples

FDA should mandate HACCP for minimally treated juices back to the orchard itself. Only when the source of contamination is included in the HACCP plan can contamination really be controlled.

In the sad event that FDA continues in its final rule to require HACCP only at the juice processing level, it is absolutely imperative that FDA mandate standardized, national SSOPs and GMPS for fruit coming into a minimally processed juice production plant. Across the U.S., SSOPs and GMPs are neither standardized, consistent, nor effective in reducing the risk in raw juices and neither is the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. As S.T.O.P. has mentioned repeatedly, the State of Massachusetts' formal GMPs for the production of cider specifically allows the use of drop apples(9). Drop oranges were implicated in the Florida orange juice outbreak (see above comments by Dr. Patricia Griffin, CDC).

In its standardized, federal SSOPs for fruit coming into a juicing process, FDA absolutely must formalize a ban on the use of drop fruit for minimally treated juices. If FDA had implemented this single requirement in 1990, assuming industry had adhered to it, more than half of raw juice outbreaks in the 1990s would never have occurred, at least one child would not have died, and dozens would not now be facing a lifetime of deleterious health consequences.

It is even more critical that FDA mandate specific SSOPs and GMPs if FDA prefers to believe what industry members alleged at the December 1999 meetings: that outbreaks are the result of the breakdown or utter lack of SSOPs and GMPs in the plant. These standards are not something FDA can just wave its hands at or leave as an exercise to its reader. When members of the raw juice industry do not understand the importance of cooling fruit prior to immersing it, when they do not understand that 200 ppm of chlorine in pH level 8-10 water is insufficient to kill off organisms, when members of industry do not understand how different waxes might encourage or inhibit bacterial growth, then it is critical for the federal government to step in, educate them and then require them to do it properly.

When the HACCP rule is finalized, S.T.O.P. strongly urges it to create a model plan which industry can follow. Industry has come to the FDA repeatedly looking for realistic guidance. At the November, 1998 Workshops, Mark Isaacs, President of Sun Orchard, indicated his company had implemented FDA's Proposed HACCP rule months prior to his company's causing the largest raw juice outbreak in U.S. history. With management having declared Sun Orchard had fixed the situation and with FDA standing by allowing them to begin shipping again, they then inflicted additional Salmonella contaminated juice on unsuspecting consumers. Industry needs more from FDA than vague discussions about where the critical control points might be: it needs a specific actionable outline of a plan, with a discussion of critical control points and how different manufacturing techniques might have an impact on the relative safety of the juice.

HACCP plans must incorporate all seven principles and plans must be validated by government. Reduction steps must be validated by science. S.T.O.P. is asking that all HACCP plans include a heat pasteurization critical control point (CCP) until alternative processes are proven to be as safe and as reliable as a heat-pasteurization kill step. If there were circumstances where FDA did not mandate heat pasteurization, a HACCP plan for such a process would have to include testing of

incoming fruit and final product. It would also need to include a reasonable hold-before-ship period to delay the shipment of potentially contaminated juice that might get into commerce.

As mentioned previously, consumers need protection against producers regardless of whether they are big or small. FDA's exemption of juicers producing less than 40,000 gallons is unacceptable. Florida's exemption from inspection of juicers selling less than 30,000 boxes is also unacceptable. Indeed, that FDA might accept Agricultural Marketing Service data as complete is also suspect because as the marketing branch of USDA it has an inherent conflict of interest. A significant percentage of raw juice outbreaks and recalls have been caused by small or even seasonal producers(10) . If, as industry has posited, the bulk of raw juice outbreaks are the result of breakdown or utter lack of sanitary operating procedures and good manufacturing practices, then the FDA must propose national standards for juices that are minimally treated or untreated for pathogens. Likewise, FDA cannot continue to ignore the roll of juice bars, restaurants and grocery stores as vehicles for foodborne disease.

VII. In Conclusion

As indicated here and in our previous public comments, S.T.O.P. doesn't have the confidence that FDA's Proposed HACCP Rule for Juice will adequately protect consumers. Though we feel FDA has taken many appropriate steps toward a better rule, and though we feel the tests for internalization show that FDA is working hard to understand all factors involved, we do not feel that consumers should bear the brunt of industry experiments with new technologies while the NACMCF awaits more data. We remind FDA that it is not expected to protect the public health from the leading edge or average producer but rather to protect it from all producers.

We concur with FDA that the pathogen reduction process must be applied where the preventative treatment has intimate contact with the pathogens, i.e. on the juice itself. We feel strongly that heat pasteurization has been proven effective at protecting the public health from the threat of pathogens in milk and that it should be used effectively in juice until such time as alternative technologies are available and while awaiting more science. No more people should have their health unwillingly sacrificed so that raw juice companies can continue to profit.

Sincerely

Laurie Girand
Advisory Board Member

Nancy Donley
President
Mother of Alex

Endnotes

(1) Given as high as 100 degrees Farenheit in the Coachella valley.

(2) Fox, Nicols, "Spoiled: The Dangerous Truth About A Food Chain Gone Haywire," BasicBooks, 1997, p. 128.: "But when investigators saw how the oranges were harvested, the possible routes of contamination became clearer. They were handpicked, but from where? Often, they discovered from off the ground. Juice oranges were shipped, without washing, to the processor. Orange growers are using chicken manure as a fertilizer more frequently. Although neither grower who had sold oranges to the processor during the period when the juice had become contaminated had used chicken manure on his fields, it was used on fields nearby. Moreover, while all the oranges sampled from one grower tested negative for Salmonella, the bacteria was found when swabs were obtained from the soil around the orange trees."

(3) Letter to FSIS Docket Clerk (Docket #99-054N), by the American Fresh Juice Council, dated 11/30/99, stated, "In regards to 'alternate technologies,' there simply are not any viable alternatives to pasteurization. Alternate technologies are either unaffordable or ineffective on opaque juice products. Countless discussions have centered on this subject, only to identify pasteurization as the only viable alternative for citrus juice."

(4) "Potential for Infiltration, Survival and Growth Of Human Pathogens within Fruits and Vegetables," FDA/CFSAN, 11/99: "Hill and Faville (1951) inoculated citrus fruit and found that there was a 3-log increase in bacterial numbers over 5 weeksThe authors noted that all control fruits appeared to be sound, including the one with unusually high counts. If control fruit, including the highly contaminated fruit, were used to make juice, the juice would have contained a count of 50,000 cfu/ml of yeast and molds. The authors stressed that the external appearance of the inoculated fruit gave little indication of the high counts that were present and would seldom be rejected by experienced graders."

(5) Definitions of fruit grades are typically established by USDA. See our previous comments for definitions of juice grade apples.

(6) Robert L. Buchanan, Letter to the Record, dated 6/15/98. "There were no quantitative data available on the levels of E. coli O157:H7 that could be expected in apple cider. There were indications that E. coli biotypes 1 can be isolated ocassionally(sic) from fresh juices, though the levels are typically low, i.e. less than 10 cru/ml. Assuming that these E. coli could potentially be enterohemorrhagic strains, the Working Groups reasoned that this initial level of 101 cfu/g would have to be reduced to less than 1 cell per serving or <10-2 cfu/g."

(7) 10/96 Cider outbreak of Cryptosporidium in NY implicated well water that had been used to rinse the apples, and pond water that had been used to make pesticides. 10/99 cider outbreak of E. coli O157:H7 in OK found tap water had coliforms in excess of acceptable limits. 5-6/95 orange juice outbreak of Salmonella showed surface water used for irrigation. 6-7/99 orange juice outbreak of Salmonella identified the potential for contamination coming in on ice that was used to chill the juice.

(8) Despite FDA assurances to industry at its 7/99 meetings, drop fruit HAS been implicated in multiple outbreaks: 10/91, Massachusetts cider outbreak, drop apples were used; 1993, Maine cider outbreak, students shook apples off of trees onto ground at edge of pasture; 1996 Connecticut cider outbreak, drop apples were used; 1995 Florida orange juice outbreak, Dr. Patricia Griffin of CDC says, "The oranges were often knocked from the trees onto the ground, and later cultures of both soil and the surfaces of oranges yielded salmonella." For additional sources for this data, see epidemiological results of each separate study.

(9) Sanitary Operating Procedures for Massachusetts Cider Mills, Food Protection Program, Division Of Food and Drugs, Massachusetts Department of Public Health, 5/12/97

(10) S.T.O.P. has cited references to contamination coming from small and retail producers in its 1/19/99 Comments on the Technical Scientific Workshops as revealed in data from Florida and from the FDA 1997 cider inspections. In addition, the 1991, MA cider outbreak, the 1996, CT cider outbreak, the 1999 OK cider outbreak, and the 1997 MI recall of apple cider appear to have been caused by small producers. Orange juice produced at restaurants or resorts, which can be considered small production, caused the 7/89 NY outbreak and the 10/89 CO outbreak.

Data Refuting 5-Logs As Sufficient Kill in Juice

- Flaws in Development of 5-Log Standard
- Consumption of Juice Underestimated
- Levels of Contaminant in Feces Underestimated
- Fruit for Juice is Usually Considered "juice grade" - Ignored
- Growth of Pathogens on Fruit
- Quantity of Contaminated Fruit Underestimated
- Final Contamination Rates in Juice Underestimated
- Pseudo-validation with Insufficient Standards

A number of assumptions were made by the NACMCF; assumptions that in the last three years seem to have been proven less and less valid and are pertinent to issues of both multiple reduction methods and the overall sufficiency of 5 logs. Here are seven key points that we believe refute the validity of 5-logs: (slide)

1) The committee underestimated the amount of juice the at-risk group consumes. The committee assumed the average individual would drink only 100 ml or three ounces of juice a day. (1) Yet, a letter from Roger Suchyta, Associate Executive Director of the American Academy of Pediatrics to the FDA dated 1/31/97, indicated: "A recent unpublished survey of mothers of children less than 6 months of age

showed that 70% of babies less than 6 months of age drink juice, and 20% of those babies drink at least 16 ounces of juice a day. Ten percent of the infants drink 24-42 ounces of juice a day. The survey also assessed juice consumption of infants 7-12 months of age. One hundred percent of these infants consumed fruit juice and 20% consumed at least 12 ounces a day with 15% consuming more than 15 ounces a day."

2) The committee assumed a low number of pathogens in animal feces. The committee worked with an assumption of levels on an order of 10 to 4 to 10 to 5.(2) However, at the Florida citrus juice meetings last November, Jur Strobos indicated that, "When you have fecal contamination, the level of pathogenic organisms that you get in a fecal contaminant is usually in the 10 to 11 or 10 to 12 range." (3)

3) The committee ignored that fruit that is sold for juice production is generally of a lower quality than fruit that is sold for commercial sale.(4) Scarring, dimples, microscopic holes, and other deformities are presently acceptable in juice grade fruit and increase the probability of uptake and therefore the likelihood and levels of contamination, issues that S.T.O.P. has raised repeatedly in its public comments.

4) The committee ignored favorable growth conditions of pathogens on fruit prior to harvest, during harvest, during transit or in storage prior to juicing. The optimal conditions for growth of pathogens is close to human body temperature. If you combine pathogens on fruit with the 90-plus degree heat, light and humidity in the kind of climate under which oranges are grown and harvested in southern climates of different states, you've optimized for much higher growth rates beyond the rate of initial contamination.

5) The committee underestimated the quantity of contaminated fruit in a batch, presuming that only a "very small number of fruits in any one batch would be contaminated...Using a relatively conservative estimate, they assumed that 1 fruit in 100 would be contaminated."(2) Fundamental practices in an industry or at an orchard may render contamination far more systematic than incidental. Examples include the use of fecal fertilizers and sprays, the use of unsanitary fertilizer, irrigation or wash water, and the practice of picking the fruit up off the ground. In these circumstances, far greater numbers of fruit could easily be contaminated than the 1% concluded by the committee. One company at the Florida meetings indicated that when they rinsed the surface of the fruit with water and common detergent, they got higher microbial loads in their juice than when they extracted juice with no rinsing.(5) FDA's 1997 survey of apple cider producers indicated that that 10% (6), not 1%, of the fruit might be picked up off the ground. And even this rate is suspect given that it was not observed but was given by orchard owners who had been educated by the US Apple Association about the hazards of drop apples.

6) The committee assumed a low rate of contamination in juice. Indeed, the committee admitted it had little, if any data on the contamination rate in juice. It therefore worked with an assumption of less than 10 cfu/ml.(2) At the Florida meetings, Dr. Martha Roberts, the deputy commissioner in Florida indicated that for 1996-1998, 4% of the samples, at approximately 5% of firms were positive for E. coli, a fecal indicator organism, and one firm had a rate of over 100 organisms per ml.(7) In a 1994 state cider inspection cited in the 1997 FDA cider report, the highest fecal coliform levels found in juice were 240 MPN/ml. (8) Preliminary research at the FDA apple cider pilot plant indicates that "typical juices made under poor conditions with poor quality fruit resulted in aerobic microbial counts of over 5

log/ml, despite incoming rates of 3 log/gram."(9)

7) The committee pseudo-validated 5-logs in juice by comparison with pasteurized eggs and fermented sausage. However, the "standard" for pasteurized eggs was developed by the marketing branch of USDA, not by rigorous testing. Indeed, even today, FSIS is not strongly supportive of 5-logs being sufficient for eggs. Repeated recalls of fermented sausage products for contamination by E. coli O157:H7 calls into question the level of safety provided by 5-logs. 13,000 pounds of salami were recalled just last week.

As of the last time the committee made recommendations, the committee did not seem to have data on the prevalence of contamination on fruit or the use of drop fruit in juice.

Re: contamination on fruit. At the November citrus meetings, Dr. Jur Strobos indicated that under laboratory conditions, "one of the things we tried to do is to figure out what's the maximum concentration of organisms that we can actually get uniformly spread around? And the maximum that we can develop is in the 10 to the 7, 10 to the 8 range."(3)

Re: prevalence of the practice of using drop fruit. The State of Massachusetts has endorsed its cider guild SSOPs which support the use of drop apples.(10) In the 1997 FDA cider survey, 37% of firms reported using drops.(11) Note that drop oranges were considered a potential source of the unpasteurized orange juice/Disneyworld outbreak of 1995.(12)

To date, nationally SSOPs and GMPs are largely voluntary and vary by state. Compliance with voluntary guidelines is not high. When FDA requested voluntary labeling on unpasteurized apple juices, its 1997 survey of cider producers indicated that only 18% of the firms labeled their produce as unpasteurized, another 9% provided a warning statement on a sign, and 5% in a pamphlets. Thus, less than a third voluntarily provided some information on juice hazards. (13). Inspections found 4% of inspected firms were operating under poor sanitary conditions. (14)

ENDNOTES

(1) NACMCF conclusion:"The Committee believes that a tolerable level of risk may be achieved by requiring an intervention(s) that has been validated to achieve a cumulative 5 log reduction in the target pathogen(s) or a reduction in yearly risk of illness to less than 10-5, assuming consumption of 100 ml of juice daily."(2) Letter by Dr. Robert Buchanan to the Record, dated 6/15/98

(3) Jur Strobos from Transcript of Proceedings, FDA Technical Workshop; Citrus Research and Education Center, University of Florida, Lake Alfred, Florida, 11/12/98

(4) Dr. Mary Lu Arpaia has given data at the 12/8/99 NACMCF meeting describing the differences between process, choice and first grade citrus. Also from USDA Definitions of "Cider grade" apples. The USDA definition of cider grade apples is: "apples which are free from decay, worm holes and internal breakdown." Grade 1 and 2 apples are "not overripe, which are free from decay worm holes, freezing injury and internal breakdown and free from any other defect, or combination of defect."

(5) Transcript of Proceedings, FDA Technical Workshop; Citrus Research and Education Center, University of Florida, Lake Alfred, Florida, 11/12/98, page 90, lines 20-25.

(6) FDA: Report of 1997 Inspections of Fresh, Unpasteurized Cider Manufacturers, Summary of Results; Inspection Findings, Harvesting Practices

(7) Dr. Martha Roberts from Transcript of Proceedings, FDA Technical Workshop; Citrus Research and Education Center, University of Florida, Lake Alfred, Florida, 11/12/98, page 35.

(8) FDA: Report of 1997 Inspections of Fresh, Unpasteurized Cider Manufacturers, Summary of Results; State Controls section; State Inspections and Microbial Sampling Initiatives.
(9) FDA/CFSAN, Potential for Infiltration, Survival and Growth of Human Pathogens within Fruits and Vegetables, reference to preliminary research at the FDA apple cider pilot plant in Placerville, CA, 1999.
(10) "Sanitary Operation Procedures for Massachusetts Cider Mills," Massachusetts Department of Public Health, Div. Of Food and Drugs, Food Protection Program, 5/12/97
(11) FDA: Report of 1997 Inspections of Fresh, Unpasteurized Cider Manufacturers, Summary of Results; Inspection Findings, Harvesting Practices
(12) Fox, Nicols; "Spoiled: The Dangerous Truth About a Food Chain Gone Haywire," Basic Books, New York, NY, 1997
(13) FDA: Report of 1997 Inspections of Fresh, Unpasteurized Cider Manufacturers, Summary of Results; Inspection Findings; Labeling,
(14) FDA: Report of 1997 Inspections of Fresh, Unpasteurized Cider Manufacturers, Summary of Results; Analysis of Inspectional Findings, The Typical Poor Operation section