SAFE JUICE PROCESSING PROCEDURES

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Dockets Management Branch (HFA-305)
12420 Parklawn Dr., Rm 1-23
Rockville, MD 20857
Fax: 301-827-6870

RE: Docket No. 97N-0511
(HACCP; Procedures for the Safe and Sanitary Processing of Juice)

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 juice. S.T.O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness. We have previously sent comments on this topic for:

- the February 3, 1997 dockets on the topic of juice safety
- the September 12, 1997 dockets for FDA's Notice of Intent on Juice Safety;
- the May 26, 1998 dockets on FDA's Proposed Rule on Juice Labeling.

Today, we are writing in support of FDA's plan to require that juice companies process juice to reduce and/or eliminate pathogens (hereafter referred to as "raw juices"). We are also writing to comment on the economic analysis that had a previous deadline of May 26.

We would like to note that S.T.O.P. learned late in June that FDA had granted an extension on the juice labeling comments that had a previous deadline of May 26. The extension was initially given just to those requesting such an extension prior to the deadline and subsequently to anyone wishing to submit those comments. We ask that in the future, when FDA grants general extensions shorter than 30 days, FDA owes it to the organizations that have submitted comments on time to notify them directly that an extension is taking place so that they may provide additional comments and cosigners to previously submitted comments.

Our comments today are organized as follows

I. Executive Summary

While S.T.O.P. in general supports regulations proposing HACCP, S.T.O.P. has identified many loopholes in FDA's Proposed Rule for juice HACCP and therefore concludes that in its current form it falls quite short of being adequate to provide the United States with safe juice. In its Final Rule, S.T.O.P. expects to see:

- all juice processors
- of all sizes (very small, small, and on up) and
- of all types of produce

mandated to perform HACCP. Those that choose not to employ a killstep must bear a warning label and perform HACCP back to the farm, the source of the produce used in juicing, which is where contamination in juice frequently originates.

S.T.O.P. expects to see retail establishments and juice bars, both of which use as ingredients bulk-processed, unpasteurized juices and sell juice by the glass or cup, develop HACCP as well, unless they process juice in 32 ounce or smaller batches and the processing equipment is sterilized between batches. In its Final Rule, FDA must also address the resale market for unpasteurized juices that are ultimately sold to consumers without being processed with a killstep so that these are not used as ingredients in an unlabeled product sold to consumers.

All juices that are not processed with a killstep must bear a warning label. As a result, S.T.O.P. does not perceive that warning labels are an interim measure, as FDA has described.

S.T.O.P. has several concerns about FDA's position that a 5-log killstep is sufficient, especially given that FDA makes several assertions in the Proposed Rule that this may be achieved with a minimum effort on the part of many juice processors. We ask that, prior to issuing the Final Rule, FDA provide the public with information about how/why the 5-log killstep is acceptable rather than just accepting and publishing the recommendation of NACMCF. We are concerned that assumptions have been made about the safety of produce that may be a matter of opinion.

All HACCP plans must be verified through microbial testing. Given that FDA's own analysis of juice processors as reported in the Proposed Rule found more than 10% of the juice producers tested had indicator organisms for contamination, we are surprised that FDA did not mandate this in the Proposed Rule. We find HACCP plans that do not include microbial testing to be of dubious value. We abhor the use of consumer complaints as the primary form of identifying that a problem has occurred in a HACCP process. Microbial testing must be followed up with inspections. FDA must address enforcement in its Final Rule. In the rule's current state, it is unclear who will be guarding the henhouse.

We strongly urge FDA to mandate written SOP's and hazards analyses. We expect that FDA will ensure that appropriate individuals trained in HACCP will be employed to create and maintain HACCP plans and implementations. We do not believe that "work experience" is a substitute for true training.

S.T.O.P. has taken considerable time and effort to develop these recommendations as FDA has taken to time to develop its Proposed Rule. However, FDA's Proposed Rule contains numerous loopholes that our proposals close. If FDA and OMB are unable to develop this type of detailed regulation for whatever reason, then S.T.O.P.'s position is that all producers must pasteurize. In the United States, juice must be made safely. FDA must halt the tide of juice outbreaks that have caused so much suffering on the part of consumers.

II. General

Because juice is made by combining many individual pieces of fruit into a larger batch, the risk of the batch increases with the quantity of fruit or vegetables involved. Juice therefore carries a higher risk than an individual piece of fruit. In combination with this fact, it is especially important that juice be safe for

consumption because children, a particularly vulnerable group to foodborne illness and death, represent a key market for juice producers. According to comments on juice labeling submitted by the American Academy of Pediatrics, 85% of infants under 6 months old consume juice and 70% consume more than 4 ounces per day. Of infants under 6 months old, 20% consume 18 ounces or more per day.(1)

A. In Support of HACCP in General

It is critical to note that consumers consider juice to be sold as "ready-to-drink," and not requiring additional preparation steps on their part. FDA market research referenced in the Juice Labeling Proposed Rule describes that consumers in focus groups indicated that "safe handling" language in a label was superfluous specifically because consumers will buy "ready-to-drink" pasteurized (or equivalently treated) juice rather than purchase raw juice and heat treat it themselves. Therefore, the onus must be placed on industry to provide a safer product.

S.T.O.P. strongly supports the prevention philosophy of HACCP. We have been active participants in FSIS' development of its pathogen reduction/HACCP regulation of the meat and poultry industry. But we have been steadfast in maintaining that HACCP alone is not a replacement for product and facilities inspections and the crucial need for microbial testing. A HACCP plan must be validated and verified and the method to do this is through microbial testing. This is especially important in the case of juice.

B. Consistency Needed in HACCP Standards

To ensure the safety of our food supply, S.T.O.P. considers it important that FDA develop regulations in a manner consistent with the standards identified by other government food safety organizations as crucial to food safety. Yet, the mandates, statutes and regulations imposed by FDA vary substantially from those of USDA. USDA's FSIS is required to conduct continuous, carcass by carcass inspection of meat and poultry products, and applies a seal of approval to inspected products. FDA merely inspects for adulteration, while FSIS inspects and provides through a seal the approval for products to enter interstate commerce. Product that fails FDA inspection can be shipped, but product that fails FSIS inspection may not enter commerce. FDA inspects plants on average once every ten years, but FSIS inspects plants every day. In fact, withdrawal of FSIS inspection virtually closes meat and poultry businesses. Plants under FDA jurisdiction rarely see an inspector.

While both FDA and FSIS have implemented HACCP programs, these programs contain significant differences. FDA's seafood HACCP plan doesn't include microbial testing. FSIS' meat and poultry HACCP plan includes generic *E. coli* and *Salmonella* testing, and a moving window of *Salmonella* contamination targets. FSIS has declared O157 an adulterant in ground beef and maintains a random sampling program to encourage voluntary testing and to remove contaminated product from the marketplace. Under FDA seafood HACCP, the first inspections conducted after HACCP implementation are considered "educational," but companies inspected under FSIS meat and poultry HACCP are expected to comply with the regulation as soon as they are implemented.

When the two HACCP programs are compared, it is clear that the FSIS HACCP program provides far better food safety protection because it is aggressively enforced, places responsibility for food safety on the processor, and clearly

establishes pathogen specific contamination levels. We strongly recommend that FDA convert its concept of HACCP to more closely match FSIS' model. Vital elements to that conversion would include: more frequent inspections, incorporation of microbial testing to validate plans, less lenient inspections, and pathogens defined as adulterants.

C. Outright Errors in FDA Juice Documents

S.T.O.P. is very concerned that FDA was unable to get an accurate list of all outbreaks from the Centers for Disease Control and Prevention and disseminate that information throughout its organization to prepare for this regulation. For example, the HACCP Proposed Rule specifically refers to two Cryptosporidia outbreaks under section IA. Microbial Outbreaks. These two outbreaks caused close to 250 cases of foodborne illnesses. Yet, in its economic analysis document, Table 15, FDA lists at most 20 sicknesses associated with Cryptosporidia in the same time period. Similarly, in the juice labeling Proposed Rule, FDA made a mistake in which it described the total number of identified illnesses attributed to the Odwalla outbreak to be 66, when the final count was 70.

It is crucial that FDA obtain accurate data on outbreaks from the Centers for Disease Control and Prevention and ensure that it is disseminated correctly throughout its organization and in the Federal Register for the following reasons:

1. Incorrect data leads to incorrect analysis and conclusions.
2. If the data is not accurately disseminated through FDA, FDA Proposed Rules become internally inconsistent.
3. When FDA publishes data, it is considered to be accurate and therefore has a higher air of authority, regardless of whether the data is true or not.
4. Publishing inaccurate data leads to its widespread dissemination in the press as though it were fact.
5. With understated data in particular, the real numbers, the press, consumers and industry cannot recognize the severity and urgency of the problem.

The CDC is usually aware of the most recent, corrected data on prior outbreaks, regardless of whether the data has been published yet in an official medical journal. In addition, CDC should be actively soliciting data from the states. S.T.O.P. strongly urges that, for any proposed rule, FDA develop through direct communication with CDC a single, accurate table that lists all known outbreaks and associated data, including:

- the food product and contaminant (e.g. juice, Cryptosporidia)
- states affected
- number of cases
- age ranges of those affected (1-5, 6-10, 11-15, etc.) and quantity in each range
- number of cases with complications such as HUS or neurological damage
- the number of fatalities
- potential identified sources of contamination, if available.

An example of this table for apple cider outbreaks in the 1990's is in Appendix C, though it is missing data that is not easily available publicly. This table would be

distributed internally within FDA during the writing of a rule and published in the Proposed Rule and in the Federal Register. It could also be given to FDA's public relations department for distribution to the press. In this manner, FDA could become a source to trust with regards to having the latest data rather than replicating data that was issued over a year ago and is inaccurate.

D. Objections to the Exemption of Harvest, Picking or Transporting

For three reasons, S.T.O.P. is very concerned that FDA has exempted, from the proposed HACCP rule, practices associated with growing and delivering produce:

"Processing means activities that are directly related to the production of juice products. (2) For purposes of this part, it does not include: (i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing."

First, in identified outbreaks, the contamination of the raw produce has often occurred at the farm level; for example, by picking apples up off the ground, by fruit grown near cow pastures, by rinsing fruit with water from a nearby contaminated well.(2) *Cross* contamination usually occurs during processing. Directing all efforts at processing long after the initial microbial contamination has occurred seems of dubious value if the original source of the contamination is not addressed. To allow produce to continue to be grown, harvested, and packed under conditions that increase the safety risk of the fruit or vegetable prior to its going into juice defeats the purposes of HACCP, control of Critical Control Points from Farm to Table.

Second, the idea that FDA is going to rely on its "Guide to Minimize Microbial Contamination in Produce" instead of HACCP at the farm is particularly worrisome. The Guide is inadequate for reducing microbial contamination (see S.T.O.P.'s comments to the dockets dated 6/26/98). It is strictly voluntary, does not include any requirements, and has no enforcement plan. To rely on this document to ensure that produce coming into a juicing process is unacceptable.

Third, S.T.O.P. strongly objects to the use of paperwork in lieu of inspecting the site that is the source of produce. Signatures do not ensure the safety of our food; actions do. As one juicer told us: "You get what you inspect, not what you expect." At a recent public meeting, food industry trade associations confirmed the importance of on-site food inspections over paperwork. A representative of the American Meat Association stated, "...you can't just simply look at pieces of paper and make a judgment call whether the product is going to meet your requirements or whether the facility is a good facility or a bad facility, et cetera. You have to actually go in as a customer and see what they are doing..."(3) FDA must address onsite inspection of all produce suppliers by outside verifying agencies to ensure that they are supplying produce grown under hazard-reduced conditions.

S.T.O.P. has consistently supported Farm to Table HACCP for juice which would reduce the need for a killstep by addressing the contamination at its source. Indeed, farm-to-juice HACCP in the orchard has already been completed cost effectively by one grower, McAfee Apple Gardens, which is now selling apples to Odwalla. We have included a copy of a description of the McAfee Apple Gardens Experience with HACCP in Appendix A of this document for reference. Given the lax growing, harvesting, packing and transporting conditions supported by FDA in this document we cannot

envision a HACCP plan without requiring a killstep. Growing, harvesting, packing and transporting must be addressed in any juice HACCP plan that does not mandate a killstep.

E. Objections to the Exemption of Retail Establishments

S.T.O.P. does not understand the exemption that FDA has given to retail establishments under section 120.3(h)(ii) in which it states:

"Processing means activities that are directly related to the production of juice products. (2)For purposes of this part, it does not include: (ii) the operation of a retail establishment."

A significant percentage of raw juice is sold by the glass. To date, Jamba Juice, a California-based juice bar franchise, has at least 32 juice bars. In a February, 1997 New York Times article, Jamba Juice officials stated that their businesses grossed between $300,000 and $1,000,000 per storefront. If there were only 200 other juice bars (which is a low estimate) in the U.S., and they and Jamba Juice's stores averaged only $300,000 per store, the Juice Bar market alone would be worth $69,600,000.

Storefronts such as juice bars, in-mall juice bars, and restaurants receive substantial quantities of bulk, unpasteurized, unlabeled juices which represent a significant hazard to the consumer. A recent article in the Chicago Tribune described a mother who was having her children drink unpasteurized apple juice at a restaurant. She had not allowed her 18 month old to drink it, but had given it to her 6 year old and her 10 year old.(4) Jamba Juice specifically touts its concentrates ***which have "not been heat treated and therefore have superior flavor."*** (5) FDA must consider the safety levels of businesses such as JR Woods (Atwater), VacuDry (Sebastapol), MetWest Agribusiness (Del Rey) in California which buy fruit and vegetables and supply juice or concentrates to retail storefronts. ***Without regulation of these additional channels for bulk raw juices it is quite possible that large quantities of unpasteurized juice will continue to be widely distributed without warning labels, pasteurization OR HACCP plans.***

Unfortunately, safety education efforts by the "juice" industry and government have targeted only juice producers closest to growing the fruit and not juice producers across other segments, such as juice bars and grocery stores. It appears that the farther away processors are from the raw fruit industry, the less aware processors are likely to be of the potential problems for contamination in juice. As anecdotal information we offer a grocer indicating he would sell raw orange juice into an elementary school lunch program because "we squeeze it ourselves on site." It is quite possible that juicing equipment in stores is cleaned less frequently than the average apple press. Another example is that of a juice bar which was determined to have purchased wheat grass grown in raw manure.(6) In short, these segments and their employees are not receiving information about how to improve juice safety.

Because it does not in any way address the "immediate consumption" segments, FDA's Proposed Rule, in combination with the Juice Labeling Regulation is creating an imbalance in the marketplace by requiring only the "later-consumption" large producers adopt safety processes. As a result, we believe that raw juice processors will feel pressured to sell their products

into market segments where they are neither required to label nor pasteurize and where consumers will not receive proper warning.

Therefore, if FDA continues to support exempting retail establishments from full HACCP, S.T.O.P. expects FDA to set national standards for safe juice processing at retail. These would include sanitizing of equipment at appropriate intervals and external verification that equipment and the juicing area do not harbor pathogenic microorganisms. Such standards must be incorporated into the model food code.

If FDA must exclude restaurants and juice bars from juice HACCP, then we would recommend that FDA define these businesses by the size of the batch: exclude from HACCP only those businesses that process juice in 32 ounce (and fewer) size batches as long as they do not incorporate juice ingredients that come from larger batches that have not been processed with a killstep. Indeed, risk analysis supports that, all other things being equal, the less fruit and vegetables that go into a batch, the lower the risk. FDA could also exclude retail establishments that sell juice in glasses that can be washed and reused.

F. Objections to the Exemption of Very Small Businesses

In its preamble, section D9, FDA states:

"FDA agrees that exemptions from HACCP regulations cannot be justified on the basis that a business is small because food hazards that are reasonably likely to occur in the production of most foods occur regardless of the size of the firm. The agency also agrees that any exceptions to mandatory HACCP systems must be based on instances in which risks are not reasonably likely to occur. However, FDA is required by law to consider ways to assist small businesses when it implements regulations. While FDA does not propose to exempt any small businesses from the food safety requirements in this proposed rule, FDA is considering ways to provide regulatory options that will serve to reduce the burden of compliance on such small businesses."

Yet, within the body of the Proposed Rule, FDA has indicated that it plans to exempt very small businesses from the HACCP requirements [**bold** is our emphasis]:

"Processing means activities that are directly related to the production of juice products. (2)For purposes of this part, it does not include: (iii) The operation of a retail establishment that is a very small business and that makes juice on its premises, provided that the establishment's total sales of juice and juice products do not exceed 40,000 gallons per year, and that sells such juice (A) directly to consumers or (B) directly to consumers and other retail establishments."

To define small juicers as "retail establishments" specifically for the purposes of excluding them is capitulation to industry processors. This definition excludes thousands of juice processors, and would in all likelihood exclude several of the processors that were the source of outbreaks.(7) We find it unacceptable to offer exclusions to the businesses that have been the very sources of contamination causing deadly illness.

Although FDA exempts small businesses by defining them as retail establishments, FDA then acknowledges:

"FDA has tentatively determined that the hazards, especially microbial hazards, inherent in juice processing are such that, unless there is adherence to HACCP principles, there cannot be assurance that the product is safe. Thus failure to operate a juice processing operation in accordance with HACCP is itself an insanitary condition that may render the juice product injurious to health."

In short, to require HACCP of only the larger producers is to continue to support the production of a hazardous product by small and very small producers at significant risk to the public health. Therefore, roadside stands selling less than 40,000 gallons per year of juice MUST be addressed in this regulation, not exempted from it. S.T.O.P. vigorously maintains that the size of an establishment must not be a factor in food safety policy. The same food safety policies should apply to all businesses. Consumers should be equally informed and protected regardless of the size of the business. Foodborne illness victims do not care whether the source of their illness was a small family establishment or a huge conglomerate. We demand the same level of protection, regardless.

When FDA chooses to treat small businesses differently than larger businesses, it raises an important question: How much of raw juice is produced by what FDA categorizes as "small" producers? (e.g. what is the concentration of the market by size?). S.T.O.P. believes that even before FDA begins considering exemptions, it should be confident that it is not exempting a significant percentage of the market.

Raw apple juice, for example, is a market that is highly concentrated at one end, with perhaps 20+ producers selling more than 40,000 gallons, and an estimated 2000+ selling less. FDA has obtained its data from the U.S. Apple Association; yet, even the U.S. Apple Association admits that it has not identified all of the raw apple juice producers in the country. If the number of producers are:

- 40 producers selling more than 40,000 gallons of unpasteurized juice
- and 2000 selling less than 40,000 gallons of unpasteurized juice,

and the average sale of the 40 producers is 800,000 gallons, while the average of the 2000 is 10,000 gallons, then regulations that apply to only the 40 largest producers will cover only 32 million gallons, while the rest of the industry produces 20 million gallons.

We recommend that FDA conduct economic analysis to verify the U.S. Apple Association data, taking into account both changes in the market since the data was collected and the fact that USAA has not identified all apple juice processors. S.T.O.P. believes it is quite possible that a number of the larger producers covered by USAA's survey have chosen to pasteurize, which would support the argument that small producers represent a more significant portion of the raw juice market than they did even a few years ago.

Indeed, in the apple cider industry, the seasonal production of unpasteurized juice is a byproduct business, one to squeeze extra margins from produce that otherwise cannot be sold to retail stores because it does not meet commercial apple grade standards. USDA-defined "cider grade" apples are apples that have defects, whether

cosmetic or damage-related such as bruises, as when an apple falls onto something. Because the byproduct business is not the main business and does not turn out the same percentage of profits, growers are reluctant to invest money to improve the safety of these processes unless they are mandated to do so. (At an estimated profit of 16 cents(8) per gallon when sold to a retailer or 32 cents if sold direct, a juicer producing 10,000 gallons would make between $1600 and $3200.)

Juice HACCP must be applied uniformly to businesses, whether large, small or very small. As FDA has stated, "any exceptions to mandatory HACCP systems must be based on instances in which risks are not reasonably likely to occur." The evidence shows that very small businesses cause outbreaks.

G. Consumer Education Must Include Consumers

S.T.O.P. supports FDA consumer education campaigns that actively involve consumer organizations and target at-risk groups. However, to date, FDA's consumer education activities have been vague and ill-timed, and affected industries have been over represented in participation and development of such programs. As an example, FDA's 1997 education campaign concerning the risks of cider was implemented too late to be effective. A letter from CFSAN Director Shank was received and posted at a California elementary school in January, three months after the cider season had ended.

We strongly concur with FDA that consumer education campaigns are insufficient to appropriately warn all appropriate consumers. Consumer education campaigns are merely supplemental to the overall regulatory process.

H. Inappropriate Examples of Produce that Might Produce Pathogen-Reduced Juices

Repeatedly throughout its document, FDA uses orange juice as an example of a juice that might not need pasteurization because of the peel:

"Because pathogens are not reasonably likely to be present in the interior of an orange, surface treatment could be adequate to ensure the safety of the juice."

In section M. Pathogen Reduction, FDA even goes on to suggest that apple juice may be able to avoid pasteurization in achieving a safe product:

"FDA anticipates that manufacturers of other juices, such as apple juice, may be able to use other technologies and practices in lieu of pasteurization (such as a combination of eliminating use of drops, brushing, washing, and using sanitizers) provided that the process is validated to achieve the 5 log reduction of the target pathogen."

In Section D1, FDA proposes that, there may be juice that require no steps at all to ensure the safety of the juice [*italic* emphasis is our own]:

"Firms may decide that it is necessary to incorporate a step designed to kill bacteria into their process (e.g. pasteurization), that there are alternative steps that they can

take to ensure the safety of their product, or that, given the nature of the raw materials, no steps are necessary."

We are surprised that FDA is making these assurances to industry. We would like to remind FDA that the latest science indicates that tomatoes, when put into a bath that is colder than the tomatoes, can absorb pathogens in water through the stem scar.(9) Similarly, recent studies are showing new ways in which the fruit or vegetable can be contaminated. The University of Georgia has recently learned that broken lettuce cells can allow *E. coli* O157:H7 to become internalized.(10) Devon Zagory President of Zagory & Associates, a consultant to produce processors, was quoted recently as saying,

"It turns out that the mechanical state of the cell structure in produce may be the primary determinant of microbial growth," he said. "So maybe our goal should be to reduce 'injury' to produce," thus not leaving damaged cells on which microbes can flourish."(11)

If this is true of lettuce and tomatoes, it may be true for other fruit and vegetables, even those that we consider to be protected by a peel. In addition, some studies show that produce with air cavities may be at more risk than other forms of produce.

To this data, we add that sanitizers have failed to prevent more than one juice outbreak. A recent article in Food Chemical News(12) indicated:

ARS' Gerald Sapers, reporting on new technologies for safer produce, noted "Most people feel chlorine is very effective as a sanitizing agent," but, he said, "this is a misperception." Chlorine, Sapers said, produces only a 1-2 log reduction in microorganisms.

To mislead juicers to believe that they may be able to do nothing because of the type of produce they juice has very limited scientific basis. We urge FDA to be cautious in its prediction about the relative safety of juices and combinations of processes without a scientific basis upon which to make the statements. Likewise, we reiterate that if FDA chooses to select a killstep reduction that begins at the point at which caked-on manure is washed off of produce with a hose, a 5 log reduction might be achieved, but it would not render safe juice made from that produce.

I. Proposed Measurement of the Killstep Should Begin After Washing and Brushing

S.T.O.P. finds FDA's tentative conclusion that the killstep "could be measured from the point of the processors' initial treatment of the intact fruit or vegetable" to be unacceptable. As just described, reducing 100,000 bacteria from a piece of fruit can be achieved with a hose if the initial bacterial load is high; yet, this does nothing to ensure that the final product does not harbor microbial contamination. S.T.O.P. believes that the measurement of the killstep must begin after mandatory washing and brushing of the fruit and vegetables. Unless FDA makes this a requirement, all juice processing facilities will be measuring their killsteps from dramatically different starting bacterial loads and can have very different results.

J. E. coli O157:H7 and L. monocytogenes Are Appropriate as Target Organisms

S.T.O.P. supports the selection of *E. coli* O157:H7 and *Listeria monocytogenes* as target organisms for the killstep. We find the selection of *Listeria monocytogenes* to be particularly appropriate given that FDA failed to include pregnant women in the at-risk groups on its warning label, so pregnant women will continue to believe that unpasteurized juice is healthier for them and their babies; yet, a pregnant women can be asymptomatic for a *L. monocytogenes* infection and this organism causes miscarriage and stillbirths. Zero tolerance for *E. coli* O157:H7 is an absolute requirement because the organism can be deadly in doses as small as a single organism. Zero tolerance is appropriate for *L. monocytogenes* until FDA includes pregnant women in its definition of at-risk groups on warning labels. We would encourage FDA to include *Cryptosporidium* in this list as well because it has been the source of multiple outbreaks and it has certain features that make it more resistant to alternate technologies that may be considered.

K. A 5-Log Killstep May Be Insufficient

S.T.O.P. supports FDA's efforts to encourage the development of alternative technologies to heat pasteurization:

"The safety performance criteria recommended by the NACMCF is whether the measures that a juice processor employs have been validated to achieve a cumulative 5 log reduction in the target organisms or a reduction in yearly risk of illness to less than 10-5, assuming consumption of 100 mL of juice daily."

Nevertheless, S.T.O.P. has five concerns with the assumption by FDA that in lieu of specifying a process such as pasteurization, a 5-log killstep is sufficient.

First, historically, what we have come to know about *E. coli* O157:H7 continues to be disproved. For many years it was mistakenly believed that the high acidity of raw apple juice would kill the organism; yet, this has been proven otherwise. Indeed, the organism can survive in what were previously considered acidic environments such as salami, which has caused at least two outbreaks. At the recent Institute of Food Technologists conference, scientists released new information about pathogens and increasing resistance to acidity. FDA's Robert Buchanan said that a pH level of 4.5 is currently inadequate for food safety purposes. Mike Doyle of the University of Georgia indicated that scientists were surprised to learn that *E. coli* O157:H7 can survive at a pH level of 4.0.(13) Research has indicated that some strains of *E. coli* O157:H7 survive in media with pH values as low as 2.0.(14) If a 5-log killstep is thought or proven to be acceptable today, S.T.O.P. believes a 6+ log killstep would be more prudent.

Second, we are concerned that NACMCF's interpretation of the data may not accurately represent the most resistant or most recent strains of *E. coli* O157:H7. Research is showing that pathogens of different strains react differently under stress and may be better able to survive than we have thought:

"Tom Humphrey of the Public Health Laboratory Service in the United Kingdom said research is showing that two wild type populations in bacteria, such as *S. enteritidis* PT4 and *S. typhimurium* DT104, react differently under stress, making bacteria

better able to survive some food production processes. Bacteria such as *E. coli* 0157 can increase heat tolerance by attaching to freshly exposed muscle tissue."(15)

Thus, the 5 log killstep time and temperature curves for one strain of *E. coli* O157:H7 might be only a 4 log killstep for another strain. Again, this suggests a higher killstep would be more prudent.

Third, S.T.O.P. is also concerned that NACMCF may have recommended a lower threshold of risk than consumers would consider acceptable-- specifically that NACMCF may believe there is an "acceptable level" of risk. According to a recent article,

"Michael Doyle, of the University of Georgia and a member of NACMCF, noted that the committee had considered E. coli O157:H7 in cattle in drawing up its recommendation, since there are no good data on the presence of the pathogen in produce... The 5-log figure was based on likely occurrence and a safety factor, explained Buchanan, who is also a NACMCF member."(16)

Unfortunately, we would point out that the "likely occurrence" of *E. coli* O157:H7 in apples is very low. Apples grow on trees; *E. coli* O157:H7 grows in ruminants. Yet, we have repeated outbreaks from apple cider. The "likely occurrence" of *Salmonella* in orange juice is very low; yet, we have repeated outbreaks in unpasteurized orange juice. S.T.O.P. would like to be assured that NACMCF members have not made inappropriate assumptions based on underreported data or based on their professional opinions regarding an "acceptable level of risk." S.T.O.P. does not believe there is an "acceptable level of risk" with regards *E. coli* O157:H7 to because it is so virulent that a single organism could be deadly. Therefore, S.T.O.P. seeks scientific evidence that the criteria supporting a 5-log killstep proposed by FDA will truly kill these organisms, as opposed to represent a "reasonable number" of organisms killed.

Fourth, if a killstep does not kill all pathogenic organisms, it may be possible that they will leave behind heat resistant organisms:

"According to new research conducted by the Agricultural Research Service, exposing *E. coli* 0157 :H7 to sublethal temperatures can actually make it more resistant to heat. The study showed that samples of the bacteria heated in beef gravy, but not killed, survived up to 1.5 times as long as unheated samples. The increased resistance lasted up to 48 hours. Food Chemical News reported today that in light of these findings, consumers and food processors should be aware that heating foods slowly to the final cooking temperature will not kill the bacteria that may be present."(17)

In this manner, an insufficient killstep might contribute to the mutation of the organism to withstand processes intended to kill the organisms.

Fifth, S.T.O.P. is concerned that many killsteps can be overwhelmed if a high load of organisms is introduced into the system. We do not understand how FDA's definition of a 5-log killstep in the HACCP implementation will prevent contamination from occurring, if for example, a juicer received a lot of carrots grown in raw manure for making carrot juice. Indeed, if a juicer received a shipment of oranges that had been picked up off the ground of an orchard fertilized with poultry feces, the likelihood of

Salmonella contamination might be high, and the 5 log reduction could be insufficient even though FDA asserts repeatedly that the peel would protect the basic fruit. At some point, the peel must be penetrated, and if washing and brushing do not sufficiently eliminate the organisms, the penetration action can result in contamination.

Under no circumstances should FDA consider less-than-a 5-log reduction as a killstep. We are surprised that when so many other regulations support a 7 log killstep, FDA has chosen to believe that a 5 log killstep will be sufficient for juice which has caused so many outbreaks. Prior to a Final Rule, S.T.O.P. would like to see benefit comparisons of both 7 and 6 log killsteps vs. the proposed 5 log killstep that indicate the above concerns have been addressed.

L. Inadequacies of Testing Should Not Result in No Testing

In section § 120.11 of the Proposed Rule, FDA indicates that "Verification activities shall include...At the option of the processor, the performance of periodic end-product or in-process testing." S.T.O.P. strongly urges FDA to mandate end product testing, particularly for microbial contamination. A positive result for microbial contamination would strongly indicate the failure of either the plan or a critical control point.

As FDA has indicated, it is imperative that the processor refrain from introducing juice into commerce that has been determined to be injurious to health or is otherwise adulterated. The only way to determine if this is the case is through end product testing. If it has, in fact, been already introduced into commerce, it should be immediately recalled. This would be consistent with FSIS' approach. FSIS has declared *E. coli* O157:H7 an adulterant in ground beef, actively tests for the organism through a random sampling program, and recalls contaminated product.(18) We recommend that FDA establish a similar random sampling program for unpasteurized juice. This testing program not only identifies dangerous product, it also encourages the industry to take preventive measures and conduct its own internal testing programs. We suspect that more juicers would be inclined to pasteurize juice or take other protective measure if they were potentially subject to random sampling.

S.T.O.P. also strongly supports incoming materials testing, especially if FDA develops a plan that does not require HACCP back to the growing process. As an example of when testing might be necessary, FDA uses the following example:

"For example, in cases where a processor is obtaining fruits and vegetables from unknown sources, and there is no assurance that pesticides have been correctly applied, product testing for pesticide residues is an appropriate step in a HACCP plan."

and

"For example, pesticide testing of fruits and vegetables may only need to be done when the source of the produce is new or unfamiliar to the firm."

While contamination can be spread from one piece of produce into juice, most outbreaks involving juice have involved produce that was believed to be contaminated prior to being placed into the juicing process. To only test incoming produce when the source of the produce changes is insufficient to verify the quality of incoming materials. Likewise, visual inspection of produce is insufficient to identify microbial contamination.(19) S.T.O.P. would point out once again that verbal and written assurances that produce is grown under circumstances that will not result in microbial contamination are useless without a HACCP plan from farm to juice.(20) Indeed, in the Odwalla outbreak, it was reported that Odwalla had contracts with all of its suppliers that indicated they would not ship the company drop apples; yet, a significant quantity of defective product arrived at the plant in the timeframe in which the juice that caused the outbreak was processed.

The 1994 Schwann's ice cream outbreak provides another example of the importance of auditing suppliers through microbial testing. Contaminated ice cream mix caused approximately 224,000 people to contract *Salmonella enteritidis*. Although the trucking company used by Schwann's ice cream had written instructions to thoroughly clean its trucks between deliveries, the truck that hauled the ice cream mix later found to be contaminated had carried Salmonella tainted eggs and was not sanitized before the ice cream mixture was loaded.(21)

If FDA does not support a HACCP plan from the farm to the juice glass, as S.T.O.P. supports, we believe that produce testing for microbial contamination should be an absolute requirement BEFORE the produce is turned into juice. Validation of incoming materials for microbial contamination should be ongoing, not occurring merely when there are changes in raw materials or the source of raw materials.

While we hold that there must be federal inspections, periodic testing should also be conducted by a third party laboratory independent of the processor, which should be accredited. Reports could be reviewed in a federal audit. The results of this testing should be published publicly so that consumers can have accurate information about the safety levels of their foods. We recommend publishing the results of a processors' testing at FDA's website to sufficiently inform the public.

M. All Raw Juices Must Be Addressed By the Rule

S.T.O.P. supports the position that all juices, regardless of the produce source, should be required to implement HACCP. Unlike FDA's current incarnation of the regulation, S.T.O.P. would like to see a regulation that indicates that if a juice is not processed with a killstep, a HACCP plan and mandatory warning labels should be required. Raw apple juice has become frequently associated because children drink apple juice and therefore outbreaks related to it are more easily identified... statistically, the development of HUS in children is one of the indicators epidemiologists seek. The fact that other illnesses have not been directly traced to juice should not be construed as an indication that other raw juices are not related to outbreaks or that they are "safe" as some juicers would suggest in their marketing. Likewise, repeated outbreaks associated with orange juice have indicated that despite FDA's repeated assurances that peeled fruit represents a particularly safer form of produce, HACCP should be mandated for peeled fruit.

N. Shorter Implementation Dates are Better

S.T.O.P. strongly supports the shortest reasonable implementation requirements FDA can mandate. We find FDA's suggestion that it might take a small processor 5 years to implement a HACCP program to be far too permissive. It should take no more than 2 years for a small processor to implement. It can actually be easier for a small processor to implement a juice HACCP program than for a large processor. When FSIS developed meat and poultry HACCP, they granted the smallest producers only three years, and this was partly because FSIS had to train its own inspectors. FDA does not appear to be developing similar inspection training programs. We therefore believe that all juice processors should be online within 2 years.

O. In Support of Juice Labeling for Juices Not Processed To Eliminate Hazards

Regardless of FDA's final HACCP rule, S.T.O.P. strongly supports the use of warning labels on any juice that has not been specifically processed to eliminate pathogens with a significant killstep. Particularly because we believe FDA will find it challenging to implement HACCP in retail circumstances, juice or smoothies sold for immediate consumption in a disposable single-serving or multi-serving size should also bear warning labels; as described above, many of these retail establishments resell bulk-processed, unpasteurized juices Restaurants that serve their patrons in glasses would not be required to place a label on the glass. We would expect those establishments to post warning information in accordance with similar size and location requirements for posting warnings about the hazards of alcohol and pregnancy.

In short, S.T.O.P. sees labeling belonging on products that have been processed with HACCP but without a killstep as part of the HACCP process, i.e. , companies achieving cumulative reductions through multiple steps would be required to label. S.T.O.P. cannot envision removing warning labels from juices unless they have been proven safe. We do not see labeling as an "interim" measure.

P. Final Rule Needs Enforcement

Within the HACCP Regulation itself FDA has not addressed enforcement. The regulation is far more likely to be adopted and foodborne illness reduced if FDA develops a plan to enforce it. We expect that FDA would include worker/whistleblower protection as part of its enforcement policy.

III. Specifics - HACCP

A. Section C.1 Increased Inspections

S.T.O.P. strongly supports increased inspections. There is little incentive to abide by the regulation if there aren't adequate inspections to assure compliance. When Michigan endeavored in the fall of 1997 to inspect its cider producers, it found a producer selling contaminated cider. We believe that less contaminated juice would enter commerce if FDA conducted appropriate inspections. Without increased inspections, it would be challenging to understand how FDA can provide adequate government oversight and verification.

B. Section C.3 Mandatory Pasteurization

S.T.O.P. disagrees with several of the assertions raised in opposition to mandatory pasteurization, not because we support a mandatory killstep, but because these arguments are inaccurate.

First, contrary to comments that FDA has received, the relative "expense" of pasteurization equipment is minimal. Low end pasteurization equipment costs approximately $15,000(22) these days. With even the simplest of financing and tax breaks for capital equipment, we believe this equipment is affordable by everyone except the smallest producers, who, as mentioned previously do not sell juice as a primary business but as a byproduct of their main business. According to FDA, "Many comments from small businesses claimed that they would be forced to close their operations if pasteurization were required." S.T.O.P. would like these companies to provide supporting economic evidence that shows that they will not be able to resell their fruit or juice in a market environment that supports a mandatory killstep. Based on information from industry, the profit per gallon of apple juice is likely to fall between 16 cents and 32 cents. If a juicer produces only 10,000 gallons, even at the higher margin, his profits will be only $3200. This company is not producing cider as its main business. If a company cannot afford to develop food safely, it should not be in the business of selling food. If a hobbyist ceases producing unsafe juice, he may close his juicing business down, but he will continue to make money in his main business.

Second, producers have pointed to the supposed safety record of juices. S.T.O.P. finds this statement on behalf of juice producers to show either great ignorance or willful disregard of the public health and of that of children in particular. As we mentioned in our juice labeling comments, known, identified outbreaks, arising from U.S. sourced raw juices, are as follows:

- Apple juice - *Salmonella typhimurium*; NJ, 1974
- Apple juice - *E. coli O157:H7*; MA, 1991
- Apple juice - *Cryptosporidium*; ME, 1993
- Apple juice - *Cryptosporidium*; NY, 1996
- Apple juice - *E. coli* O157:H7; WA, CA, CO, 1996
- Apple juice - *E. coli* O157:H7; WA, 1996
- Apple juice - *E. coli* O157:H7; CT, 1996
- Orange juice - *Bacillus cereus*; AL, 1994
- Orange juice - *Salmonella typhi;* NY, 1989
- Orange juice - *Salmonella hartford*; FL, 1995
- Carrot juice - *Clostridium botulinum*; WA, 1993

We believe this list represents only those made public, and that many more outbreaks and cases go unpublicized and unrecorded. In the fall of 1997, the state of Michigan recalled several hundred gallons of E. coli O157:H7 contaminated cider from Schlubatis Orchards. Exactly whether the contaminated cider caused illnesses and the severity of the illnesses was not determined. We note that the outbreaks we list are exclusively from U.S. sources. Raw apple juice has also caused outbreaks in Canada. Juice imported to the United States has also caused outbreaks. In short, unpasteurized juice has caused numerous outbreaks during this decade.

FDA needs to be very explicit with industry in describing that these illnesses are most often identified in children who develop life-threatening symptoms and conditions. Given the fact that most foodborne illness is unrecorded, it would be dishonest to assert that these represent the only illnesses caused by juice.

Third, some oppose a killstep because of a "degradation of nutritional value from heat treatment." S.T.O.P. looks for FDA to identify an existing scientific study that supports this position. Otherwise, it is conceivable that this is marketing misinformation posing as potential scientific evidence to support an untenable position.

Along side these three, producers have argued that there exists a consumer preference for the flavor of unpasteurized over pasteurized juice. This is the only argument that S.T.O.P. believes represents a true economic/market issue. It is because S.T.O.P. has recognized this demand, that we have not pushed for mandatory pasteurization as long as serious, farm-to-fork HACCP planning is developed and labeling is put in place to warn consumers.

C. Section D- Prerequisite Program Standard Operating Procedures

FDA must establish written, monitored and verified SOPs for incoming materials, specifically fruit and vegetables. FDA's draft guidance on fresh produce is inadequate as for the purposes of juice safety. Reasonable procedures for acceptance of incoming materials that could be incorporated into SOPs are:

- tree or vine/pole grown fruit must not have come into contact with the ground
- no fruit or vegetables used for juice should be irrigated or processed with water that could harbor pathogens
- no fruit or vegetables used for juice should be fertilized with compost containing animal manure or raw manure unless the fertilizer has been through a killstep
- all crates coming into contact with fruit or vegetables should be steam cleaned between lots
- sourcing farms and orchards should be inspected regularly for compliance.

S.T.O.P. believes that FDA should hold a separate meeting to ask for input on SOP's for incoming materials.

D. §120.6(a)(1) Sanitation SOP's(23) Should Be Written

Unlike FDA's current proposal, S.T.O.P. considers it imperative that all manufacturers be required to have a written Sanitation SOP plan. Particularly with regards to some small juice producers, it is unclear what sanitation practices are being followed. Juicing may presently be conducted in open-air sheds over dirt floors next to cow pastures. FDA must set standards that the industry can clearly follow.

E. §120.7 Hazard Analysis Should Be Written

S.T.O.P. strongly supports a written hazard analysis for juice. Without a written hazard analysis, it is unclear whether a producer can be confident that they have identified all potential hazards and control points.

F. §120.7(b) Other Considerations

FDA indicates that

"The agency is proposing in §120.7(b) that processors should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished food for the intended customer. "

This section goes on to describe that such a list was not developed for Seafood HACCP regulations. S.T.O.P. strongly encourages FDA to be as explicit as possible with all food producers by developing such lists as long as they are not exclusive. We would suggest that it is unclear from the above list that FDA is addressing both the ingredients and the final product when it describes "packaging and storage." We would strongly encourage FDA to include cooling, ice and water quality specifically as factors for consideration.

G. §120.8(a) Plan Must be Conducted By Someone Trained in HACCP

S.T.O.P. strongly supports FDA's requirement that the HACCP plan be developed by an individual or individuals with training. However, we do not support waiving training requirements for people who might somehow be determined to have had "equivalent job experience." If FDA supports a "job experience" proxy for real HACCP training, S.T.O.P believes it will be creating a significant loophole in juice HACCP. Few individuals in the produce industry understand HACCP today. Those that do have been trained. We support training and certification programs period. Indeed, the cost of short course training is not prohibitive.

HACCP is too precise and too critical to the public's health to be left up to someone who has not received training.

H. §120.8(b) The Contents of the HACCP Plan

Ironically, though FDA does not require HACCP of produce providers to a juicing process, it indicates that [*italics* are our emphasis]

"The HACCP plan shall, at a minimum: ... (2) List the critical control points of reach of the identified food hazards, including as appropriate:... (ii) Critical control points designed to control food hazards introduced outside the processing plant environment, including food hazards that occur before, during, and after harvest."

As previously indicated, S.T.O.P. strongly supports HACCP back to the grower. If a grower does not employ HACCP but supplies produce to a juice processor, S.T.O.P. is at a loss as to how the control points "before, during, and after harvest" will be controlled. The distinction we prefer to see in the Final Rule is that any juice processor that does not employ a single, significant killstep reduction such as pasteurization must do HACCP from farm to fork, i.e. companies achieving cumulative reductions through multiple steps would also be required to do HACCP from before harvest. If the company uses a killstep such as pasteurization, then the company could limit its HACCP to the juice process as FDA describes.

We suggest that FDA develop generic HACCP models to facilitate understanding and implementation of a sound HACCP plan. FSIS has done this for meat and poultry plants. Models would address the objections and concerns of smaller processors including those that FDA defines as retailers.

I. §120.11(a) Verification

As mentioned in section IIL above, microbial testing must be used for verification of the HACCP plan. It is unacceptable to use consumer complaints as the chief form of verification. S.T.O.P. would suggest that companies that pasteurize or achieve the reduction through a single killstep would be allowed to perform microbial testing slightly less frequently than those that did not employ a killstep as part of the HACCP process. While we believe consumer complaints should be used as verification, they should be the absolute last step in a multi-step process of verification to ensure that juice is safe.

J. §120.11(b) Validation of the HACCP plan.

FDA has indicated that "The validation shall be performed by an individual or individuals who have been trained in accordance with §120.13 and shall be subject to the recordkeeping requirements of §120.12." It is imperative that FDA require that an independent third party validate the juice processor's HACCP plan.

IV. Specifics - Economics

S.T.O.P. has several concerns about the economic analysis, for which comments were due May 26, 1998.

A. Market Size and Segmentation

S.T.O.P. is highly concerned that FDA has underestimated the overall size of the raw juice market by ignoring several segments. As we have already described, we strongly believe that juice bars must be included in FDA's market segmentation. We believe that grocery stores as well sell more unpasteurized orange juice than the economic analysis suggests; grocery store chains or retail trade associations should be able to provide you with this information. Further, we believe that FDA must examine the issue of concentrates that are developed without pasteurization and which may represent a significant public health threat as ingredients in other products or when sold as frozen juice. Our Appendix B contains information from our original Juice Labeling comments suggesting a method for segmenting the market.

We believe that FDA has overlooked the fact that a significant percentage of raw cider producers consider cider production as a byproduct business--"cider grade" apples are apples that cannot otherwise be sold at retail as whole fruit because of defects. Thus, cider can be a way of generating additional income from lower quality fruit. It stands to reason that similar low quality produce may be used in the production of other raw juices. To the extent that this produce contains imperfections in the skin or surface of the produce, allowing contamination to penetrate the fruit or vegetable and escape surface washing, the produce used in juicing may be more at

risk of contamination than commercial grade produce and therefore may make this class of raw juice even more risky.(24)

We ask that FDA conduct a more accurate economic analysis including all segments described in our Juice Labeling Comments because we believe that FDA's assertion that 98% of the juice sold in the United States is pasteurized may be incorrect and results in a false complacency as well as a false sense of security. We also believe that at certain times of the year and in certain regions, such as during the fall in New England, when a significant percentage of unpasteurized apple juice is squeezed, it is possible that raw juices make up a far more significant percentage of juice in a given region.

B. Market Trends

While the devastating juice outbreaks of the fall of 1996 have convinced some larger juice processors to pasteurize, we also ask that FDA examine trends in consumer consumption of fresh juice. Demand for raw juice and smoothies has been on the increase for some time in California and other states with warmer climates.(25,26) Likewise, identification of foodborne outbreaks associated with juice have been increasing. The economic analysis does not appear to take into account some of these longer term trends which strongly support the need for HACCP and labeling in both small and large businesses. While some large apple cider companies such as Odwalla and Zeigler's have moved toward pasteurization, smaller companies, such as Wiman's, continue to emerge selling unpasteurized juice to meet uninformed consumer demand. We would encourage FDA to examine overall market trends with respect to raw juices.

C. Economic Evaluation of Illnesses

S.T.O.P. is concerned that the economic evaluation of illnesses related to E. coli O157:H7 underestimates both the short term and long term costs. In the Odwalla outbreak, 20%, not 10%, of reported cases developed HUS. Once Hemolytic Uremic Syndrome complications begin, the cost of hospitalized care is high and may continue for months. Survivors are at risk of a host of potential long term complications, including high blood pressure, gall stones, pancreatitis, diabetes, and kidney failure--many of which were not addressed in the economic analysis. We would ask FDA to speak to a number of specialists to gather appropriate data describing the risks facing survivors.

D. Effectiveness of Labeling

S.T.O.P. vigorously disagrees with FDA's assertion in the economic analysis that labeling will result in low levels of illness reduction by the parent/child at-risk group in particular. If FDA were to analyze the age data for victims of juice related outbreaks, we believe it will find a significant majority of illness cases are those associated with children. To determine the effectiveness of labeling in preventing illness, FDA would be better served by looking at examples of successful warning campaigns to parents, in particular. Health/protection related campaigns, such as putting children into carseats, preventing children from sitting in seats related to airbags, avoiding serving honey to children to prevent Botulism poisoning, and putting children to sleep on their backs to prevent SIDS would serve as better examples of how parents respond to warnings specifically intended to protect

children. When combining the age data with effectiveness of warnings to parents, we believe that FDA will find substantially more illnesses will be prevented. Labeling is an easy, inexpensive way to advise consumers and prevent tragedies.

E. Benefits of Rulings

In Table 20, FDA neglects to include the savings accrued to federal government when it does not have outbreaks it needs to investigate.

V. In Conclusion

S.T.O.P. cannot support a HACCP program required for only producers of more than 40,000 gallons which we believe would exempt the majority of raw juice producers in the United States. When juice bar raw juice sales and grocery store raw juice sales are included in the total production of juice in the United States, we believe that the HACCP Rule as proposed will neither cover the majority of producers in the country, nor will it cover the majority of the servings of unpasteurized juice. Therefore, S.T.O.P. urges the following.

All raw juice producers, and of all sizes (including very small producers), and of all types of produce, must be required to develop HACCP plans for juice production that include a significant reduction of pathogens, possibly as great as a 6 or 7 log reduction, but certainly no less than a 5 log reduction. To leave a portion of the market unaddressed by these regulations and enable it to continue to process juice as juice has been processed in the past is to guarantees that outbreaks continue to occur.

S.T.O.P. supports that the juice processor should be given the choice as to whether to include a single, killstep process as part of the HACCP implementation. If the juice processor elects to achieve pathogen reduction through multiple steps, without employing a killstep that obtains a significant reduction (perhaps as great as a 6 or 7 log reduction, but no less than a 5 log reduction), that juice processor should be required to comply with two additional requirements. First, the HACCP plan must address the entire process from farm-to-fork, from when the fruit or vegetable ingredients are grown. Given the risks inherent in juicing hundreds of pieces of fruit into a batch, it is no longer acceptable to use dropped fruit or irrigating or washing the produce with less than potable water. Second, that juice must bear a warning label that indicates that it has not been specifically processed to eliminate pathogens.

If an adequate killstep is employed to eliminate pathogens, these companies should be required to label their juice with the term that describes the killstep: "Pasteurized with ultraviolet light" or "Pasteurized through pressure" or "Ultrapasteurized with heat," etc.

S.T.O.P. recognizes that for its own reasons, FDA plans to exempt retail processors. However, we are very critical of the current FDA definition of a retail juice processors because it includes a significant portion of the raw juice market that continues to operate as it always has. S.T.O.P. has been and continues to be supportive of HACCP

at retail and restaurants. However, it appears it will take some time before FDA is able to implement HACCP in retail establishments for juice. In the meantime, S.T.O.P. believes that retail establishments should be exempt from HACCP only if they produce juice onsite in 32 ounce (or smaller) batches and these batches do not include as ingredients juice processed from larger batches that have escaped processing with a killstep. Equipment must be sanitized between batches to eliminate cross-contamination. These retail establishments must place warning labels on disposable containers and cups. If raw juice is served in glasses, appropriate warning signage must be developed. At the heart of this definition is the fact that juice processed for an individual with fewer ingredients in a batch is less risky if all other factors, such as equipment sanitation, levels of contamination, etc. are the same.

Any bulk, unpasteurized juice resold for consumption to consumers must be processed with a killstep.

S.T.O.P. has taken considerable time and effort to develop these recommendations as FDA has taken to time to develop its Proposed Rule. However, FDA's Proposed Rule contains numerous loopholes that our proposals close. If FDA and OMB are unable to develop this type of detailed regulation for whatever reason, then S.T.O.P.'s position is that all producers must pasteurize.

S.T.O.P.'s solution gives consumers and producers the best of both worlds. First, through HACCP regulations that reach from farm to juice for unpasteurized juices, all juices in the United States will be held to a reasonable standard of safety to ensure that American consumers can have some confidence even in raw juices. However, consumers will not at the same time mistakenly believe that raw juices are risk-free and are therefore safe to serve to small children or seniors. Second, raw products will still be available to consumer who prefer the taste and are willing to take the risks. Third, companies that employ a killstep will be able to market the safety level of their products as different from those processed without a killstep. Lastly, consumers will also be informed that juices served by the glass in true retail establishments carry the same cost-benefit tradeoffs that consumers encounter when purchasing juice for later consumption.

S.T.O.P. asks that the juice regulations be made a part of the model food code to ensure consistency across the states.

Sincerely,

Laurie Girand
Board Member
S.T.O.P. -- Safe Tables Our Priority

Nancy Donley
President
S.T.O.P. -- Safe Tables Our Priority

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2. "'Equivalency is a two-way street,' Buchanan cautions fresh produce meeting," Food Chemical News, May 18, 1998, page 15; and Transcripts of Juice Safety Meetings, December 16, 1996; Patricia Griffin's presentation.
3. Heritage Reporting Corporation transcript, "Ground Beef Processing Guidance Materials Public Meeting," FSIS, April 22, 1998, p. 68.
4. Sue Ellen Christian, Chicago Tribune, July, 1998
5. Jamba Juice website, late May, 1998.
6. Conversation with Sacramento, FDA official, March 3, 1998
7. As S.T.O.P. perceives them, outbreaks by cider producers making less than 40,000 gallons a year in all likelihood include the Fall River, MA, 1991 outbreak; the 1996 Connecticut; and the 1996 Cryptosporidia outbreak in New York. The Schlubatis Orchards recall of 1997 may also have been produced by a processor that falls into this category.
8. Data provided by cider industry source.
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11. "Research on produce safety seeks breakthroughs," Food Chemical News, May 11, 1998, page 30
12. "Federal research agenda for fresh fruit and vegetable safety outlined by ARS researcher," Food Chemical News, May 25, 1998, page 9
13. Janet Byron, "Phs Under 4.5 No Longer the "Magic Number" for Produce, Juice Safety," Food Chemical News, July 6, 1998; page 24 and 25.
14. Miller LG, Kaspar CW, Escherichia coli O157:H7 acid tolerance and survival in apple cider. J Food Prot 1994;57:460-4.
15. "FoodNet wrestles with obtaining geographic balance, adding new pathogens," Food Chemical News, April 27, 1998, page 23.
16. Buchanan highlights fresh produce guidance areas where FDA seeks input," Food Chemical News, May 25, 1998, page 5.
17. E-mail from National Meat Association, 7/14/98
18. Verify FDA calls E. coli O157:H7 an adulterant in juice
19. See footnote 11 .
20. See footnote 8.
21. Nicols Fox, "Spoiled: The Dangerous Truth About A Food Chain Gone Haywire," Basic Books, New York, NY; page 176.
22. Goodnature Products, Letter dated 2/4/98: "Prices range from $12,700-$17,000 for our Micro Flash Pasteurizer."
23. In the preamble section of FDA's Proposed Rule, this is section D1.
24. See description of mechanical cell structure's impact on bacteria in the section above in section IIH.
25. Jamba Juice has been considered a hot franchise opportunity for more than two years.
26. Walter Nicholls, "The Juice Generation: Move Over, Latte. High-Fashion Fruit Drinks Are Shaking Up The Market," Washington Post, 7/29/98, page E01.

Appendix A

McAfee Apple Gardens Experience

The McAfee Apple Gardens Field HACCP Program
Observations from our Field HACCP Experience
January through July, 1997

First Comprehensive Field HACCP program for Apples

McAfee Apple Gardens set several goals when this program was initiated in January 1997:

1. To be America's first apple grower to join the Farm to Market/Consumer partnership for safe food.
2. To perform field HACCP cost effectively and with enhanced economic return while utilizing practices that other tree fruit growers may also readily adopt.
3. To directly forge relationships with all partners in the food safety chain including: The Scientific Auditing Lab, Growers, The Packer, The Retailer, and The Consumer.
4. To enhance food product safety while maintaining or enhancing product quality.
5. To provide apple processors with an option of Field HACCP apples.
6. To provide the consumer with the option of Certified and HACCP Farm to Market fresh apples.

We discovered that although apple processors such as raw juice producers were interested, they said we were ahead of our time and would not buy. They would rather continue to run grounders and mixed quality apples through their process.

We also discovered that this program had far-reaching impacts that we had not anticipated or predicted. A few include positive farmworker hygiene, social implications of farmworker hygiene and food preparation practices with their families at home, farm and off-farm politics, significantly lower harvest labor costs, and enhanced efficiency.

The McAfee Approach to HACCP

In order to learn the principles of HACCP, Mark McAfee, Managing Partner, took a Food Processors Institute HACCP course. This course was held at Chapman University in March 1997. Most of the people attending were in food service, science industry, food processing or regulatory branches of the FDA or USDA. McAfee was the only farmer to attend. The instructor had never seen a farmer attend before.

One of our goals at McAfee Apple Gardens was to implement changes cost effectively. We poured no concrete and bought no stainless steel. All of our modifications were made using scrap from the farm or readily available materials

from suppliers. We invented and fabricated the HACCP stations in the McAfee Apple Gardens shop. All welding was done by HACCP team members.

We wanted our HACCP program to be easily replicated at another ranch with minimal effort or expense.

Orchard Conditions and Inspections

Orchard Inspected During Irrigation

At least three times per month the orchard is inspected by ATV during fan jet inspection for signs of waste: odors, flies collecting or fecal matter etc. If any fly attractant is observed it is buried under 8" of dry soil. All paper is removed from the field if found. It is interesting to note that in March our pruning crews discovered human waste from "fence jumpers coming from a neighbor's ranch". We noted the problem, called the ranch manager, and made a complaint. He denied a problem. We showed him the evidence and our HACCP training program, much to his embarrassment. Our crews were collectively fired up about this violation of there HACCP orchard. All four piles of human waste were buried under 8 " of dry dirt per SSOP.

Comprehensive Audit By PRIMUS LABS

Primus labs comprehensively inspected documents and orchards, tested apples for pesticide residues, tested waters including fan jet irrigation system in field, worker sanitation practices, all SSOP's, the HACCP plan, equipment repairs, land and fertilizer use history, and literally hundreds of small items and issues. The results from all major audit categories are then posted on the internet for public review:

http://www.primuslabs.com/mcafee/home.html

Primus Labs takes fruit samples and checks for a broad range of chemicals. Our standard is "none detected". With the audit available online, it is felt that the quality of our program is entirely available to the consumer. This is the ultimate food safety data link.

Equipment and Resources

Picking Bags

When the contractor brought the picking bags to the cleaning station the day before our first HACCP harvest day they were covered with literally years of filth build up. A day in the life of a non-HACCP picking bag is pretty dirty. It gets used as a seat in the van. It is thrown on the ground several times per day. Workers eat and smoke over it and use it as a garbage waste basket on the way to and from work in the van. It becomes thoroughly saturated with sweat and dirt during the day. It is rarely, if ever, washed. It is replaced eventually when it fails and wears out.

A HACCP picking bag has a much better life. One day, prior to harvest it is thoroughly washed with 300ppm chlorine bleach solution and hung up on a rack to be irrigated thoroughly with potable water and allowed to hang dry overnight. A

HACCP bag never touches the ground. During breaks it is placed on a special rack on the HACCP station to prevent falling on the ground. The bag never leaves the HACCP area while in use. It is visibly clean and odor free. If it becomes dirty, an SSOP covers how to clean it. In the hot afternoon, picking bag straps do not cut into the picker's neck and shoulder area with a sweaty soil grit. The picker's back is sweaty but not soiled.

Ladders

When the contractor delivered the ladders to McAfee Apple Gardens, they were covered with years of filth from soils of the fields of the San Joaquin valley. The Hydrowash removed one quarter to one half inch layers of caked on dirt and filth from the thousands of times they had been stepped upon by workers' feet and hands.

The ladders were then modified to allow a comfortable method to move the ladder without touching the ladder rungs and steps. A handle was attached and a barrier was installed to keep the handle clean. Workers were trained on how to use this new device, how and where to touch it, and what to do if they touched it incorrectly. Workers report that it is comfortable and easy to use.

Bins

Bins that come to the farm from the shed are covered with dust, old rotten fruit, juice stains, bird droppings, fly specks, leaves, and miscellaneous filth among other things. A five gallon bucket was nearly filled with filth waste removed from the first day's bins.

After Hydrowash, bins looked bright shiny clean. The Hydrowash unit provides 3200 psi of water at 4 gpm flow. The result is an effective cutting and cleaning tool that rapidly removes filth down to a clean plastic surface. Potable water is used in this and all applications in the HACCP environment. Sterility is not our goal. Our goal is a huge biological load reduction and the elimination of cross contamination.

Field Bin Trailers

All bin trailer hitches were modified to allow attachment to the bottom 3 point hook up on the tractor. This allowed an additional 12" of space between tractor and HACCP station reducing the incidence of tractor tire contact with workers.

Forklift Operations

A SSOP covers aspects of forklift operations. Clean bins do not contact the ground and are stacked from the field bin trailer directly onto a parked hydrowashed truckbed. An inspection of the forks on the forklift shows a trace amount of rust and no loose soil. The forks are hydrowashed anytime they are used in the dirty bin area or if they become soiled. The forks are kept at a height of one foot or above the ground at all times in the clean area.

Trucks

All truck drivers are required to wash hands and receive a special information card on how to handle the load. They do not stop but go directly to the packing shed.

Special Soap

A USDA E-2 rated soap approved for use in food processing applications is used at every wash station.

Worker Training and Conditions

HACCP Certificate Training

All harvest workers are required to be certified to work. Training includes a condensed version of all important and relevant SSOP's. Some of the more interesting topics include: which things are clean in the field and which are dirty, how to stand in line for hand inspection, how to wash hands, how to not get splashed when using a field toilet, where to put paper when in and out of toilet etc., how to wash a picking bag, how to use a field ladder and not get contaminated from soil contact, how to unload full bins and never let the bins touch the ground, how to watch for bird-pecked apples and not pick them, how critical it is never pick up a dropped apple or one that has been or is on the ground, what to do if a worker accidentally breaks an SSOP, and how to make money on the violations of any visiting person.

Worker Training Curve

The training curve for farm worker HACCP behavior compliance after receiving 1.5 hours of training was very short. Few SSOP exceptions were seen by HACCP Team members. All observed SSOP exceptions were documented and addressed with apparent quick worker acceptance. None were critical.

Daily HACCP Inspection

Each worker must wash their hands and stand in a line to have their certification cards, hats, hands, nails and overall health inspected. This at first seemed odd to them but after the second day workers prided themselves on how compliant they could be. Showing off the card and having clean, well kept hands was now becoming something to be proud of.

Results of Hand Inspections

Every standing inspection found one or more workers in noncompliance with CCP or SSOP, including new workers who did not have cards, workers that had injuries to their hands from prior work, workers that had lost cards, and one that needed a bandage to cover a small healing wound. In one case, a worker was given training but not allowed to work for several days until his hand healed.

There is something special that happens when the HACCP Team Inspector talks with each HACCP worker, inspects their certification card, calls them by name, touches them and inspects their hands. Each person feels part of a team and everyone gets individual attention.

Field Hand Washing

HACCP crews seem to enjoy staying clean, and truly appreciate the allowance in our SSOP for washing their face when it is hot in the afternoon. They must wash hands after face wash. By SSOP we have calculated that workers completed at least 1500 wash cycles during harvest. In reality, we experienced at least three times this number of wash cycles. Perhaps more than 5,000 hand wash cycles in 5 days. They must wash after touching items outside of the permitted touch loop, i.e. tractor wheel, forklift controls, dirty bins, waste in basket etc.

Picking Economics

This year McAfee Apple Gardens paid $5.50 per hour, well above minimum wage to all pickers. We have never paid and do not believe in paying the minimum wage. An additional 32% was paid to the contractor to cover taxes, insurance etc. Even though wages are 9% higher this season than in 1996 ($5.00 hour), we picked our apples for much less in the 1997 HACCP program. During a 4- day pick in 1996 the daily labor cost per day per bin was:

$32.82 $30.33 $31.83 $32.23

The average cost to pick 1000 pounds of fruit was $31.80 plus about one dollar for standard forklift operations, coming to $32.80.

For the same type of fruit in the HACCP program with Hydrowash and special HACCP fork lifting, the labor cost per day per bin was:

$37.36 $27.17 $28.55 $26.92 $25.34

The first day included; 1.5 hours of non pick training time to become HACCP certified apple pickers, and also the learning curve. $ 29.06 was the average cost to harvest HACCP fruit. This included Hydrowash of all bins and special forklift operations. The bottom line is, it appears cheaper to pick fruit in the HACCP program by a factor of at least 25% (if hourly pay increase and first day training and learning curve is excluded). This factor should grow higher as the precertified base of workers grows. McAfee Apple Garden's 1997 Granny Smith harvest should reflect this economic factor.

HACCP Apple Pickers' Thoughts

Maribell, 22, mother of two. Second year working at McAfee Apple Gardens.

"Until I had this training, I just did not know about these safety problems. I have two kids... and I want them to eat clean apples like these. I like working here, I don't get all dirty and smelly all day long. I can stay clean and everything I touch is clean. My clothes don't get ruined...I feel better when I work here, I am not so tired..."

Jose, 30, Fourth year at McAfee Apple Gardens.

When asked how many times he had washed his hands during the day, he said "I lost count a long time ago." When asked again, he said "At least 40 or 50 times."

Danielle, 19, Second year at McAfee Apple Gardens.

When asked the process of handwashing at McAfee Apple Gardens, she stated verbatim the five step process: "Wet, soap and rub, wash, dry, waste in bucket."

Rafael, 19, Second year at McAfee Apple Gardens.

When Dr. Jeff Farrar of the California Department of Health Services was visiting our HACCP apple crew, Dr. Farrar attempted to place an apple he had picked without washing his hands into a worker's apple bag. The worker said softly and kindly,"You cannot do that," and then threw the beautiful piece of fruit on the ground.

Crew workers when observed had very high SSOP compliance and looked out for each others' SSOP compliance. McAfee Apple Gardens has video showing senior pickers calling out to junior pickers in Spanish asking them "Let me see your hands... where are they?" Only to have the questioned worker put up his hands to show he was in compliance.

Packing Shed Continues HACCP After Harvest

Suma Fruit International

Suma has hired a specialist in HACCP program development and implementation. The initial plan calls for a phase in of gradually more intensive sanitation practices and pseudo-kill step procedures. Ozone, Tsunami and other technologies are being evaluated.

At Suma, McAfee bins are never placed on the ground but rather, they are tagged on the truck using a special ladder. Then the forklifts are cleaned and bins are moved into designated HACCP areas that are placarded. The plastic cold air block doors are held open so that there is no contact with the bins or clean forklift when bins go through the doors. Many HACCP risk reduction practices are employed at many levels throughout the plant. All apple handlers wear gloves and hand sanitizers are found at strategic locations. Prior to the HACCP batch fruit being run, the line is sanitized, the dunk tank is thoroughly cleaned, and new water and sanitizer chemicals are used.

A special sticker is applied to the fruit to show its very special handling from Farm to Market. The carton is identified with actual grower information. And a sticker is applied to the outside stating "Safety Checked". Special storage and trucking requirements are then followed. At the consumer level special marketing and handling information is provided.

Suma Shed HACCP Observations

Forklifts never place HACCP bins on uncleaned surfaces, HACCP bins are held off the ground by the forklift until placed in precleaned areas. The dunk tank waters were visibly clean and clear after 25 bins when just a day before after 14 or 15 non-HACCP bins the water was very dirty, murky and looked like mud. At the end of packing, the water was still visibly clean when compared to non-HACCP water.

The shed walls were covered with large posters that described HACCP and food safety.

Bob Issac, the plant manager for Suma said, "You know Mark, we have put gloves and hair nets on before for the USDA and others... but when they left, every body tore them off... This is the first time it's been for real and for a good reason..."

Mary Moy, HACCP development and implementation specialist for Suma said, "...I have seen a lot of processing fruit over the years. I would feel very comfortable if a juice processor took your fruit from the field directly to non pasteurized juice for adult consumption... This is really good fruit... Field HACCP really makes a big difference..."

HarvestSafe From Farm To Market

This program is open to any interested tree fruit grower in California on a consulting basis or other custom arrangement. Any grower that brings their fruit into our program at Suma will be charged a minimal fee for a complete HACCP program.

Conclusions

We believe that HACCP goes way beyond organics to provide food safety to the consumer. Organic standards allow pesticides, allow for drift, etc. In contrast, HACCP standards state that no pesticides be detected. In organics, the emphasis is on what has or has not been sprayed or applied in the last three years. In organics, there is little or no mention of biological risk on the fruit. A.J. Yates, the Undersecretary of Agriculture for California, has said, "These biological issues are the pesticide issues of the 1990's." To reduce or eliminate all risks including those that are Physical, Chemical, and Biological, the best and most advanced food safety technology available today is "Farm to Fork HACCP." There are four equal partners in this food safety chain. The Farmer, the Packer/ Processor, the retailer and the Consumer. The certifying lab also plays a vital role in verifying compliance through this process.

President Clinton has dedicated himself to Food Safety enhancement at the highest levels. Food safety advocates have assisted in helping McAfee Apple Gardens understand the significance and value of these issues.

The Farm to Fork program initiated at McAfee Apple Gardens is a direct result of this presidential and consumer call to action. A wonderful side effect of this effort has been farm worker health and welfare.

Some farmers have expressed a negative concern to the Agricultural Commissioner about our program. They have said that the McAfee program will cause consumers to think that all other non-HACCP fruit or produce is somehow unsafe. We are not saying or inferring this in any way. America has the safest food supply in the world, and we are very proud to feed America and the world as a farmer. There is no reason to fear Field HACCP. This change is good for all partners in the food safety chain. In fact, the farmer may be the one to gain the most economically from this new concept.

Change is always hard. With the average age of the California farmer being 54 years old and very conservative, change may be hardest for this group. Many see no reason to change practices which may be 30-40 years old. Our field HACCP practices contrast sharply with traditional methods. Field HACCP, although friendly, highly organized, efficient, and cost effective, could appear to be threatening to the average farmer.

What we are saying is that we do not want to be blamed for someone else's problem; be it an International grower or an American, and lose money or market share because of a contamination episode. McAfee Apple Gardens wants to be accountable and responsible for its farm product in a way that is open and beyond reproach. We want to have a close relationship with our consumers and to provide them with what they demand:

high value, high quality, healthy, and safe food.

There is no doubt that HACCP will grow rapidly if supported and favored by the consumer.

Visit McAfee Apple Gardens at our Website:

http://www.primuslabs.com/mcafee/home.html

Alternately, Mark McAfee, Managing Partner of McAfee Apple Gardens, may be reached at 209-846-9736

Appendix B

S.T.O.P. Juice Labeling Comments
on
Market Sizing and Segmentation

Submitted on May 26, 1998

Market Sizing and Segmentation

We believe that it is quite possible that FDA has substantially underestimated the quantity of raw juice sold in the United States, perhaps by more than 100%. FDA states in both the Proposed Rule and repeated public remarks that "approximately ninety-eight percent of juice sold in the United States is pasteurized." We believe this ignores several critical juice market segments and characteristics that result in the 98% figure downplaying the importance and urgency of the juice safety issue.

Segmentation by Point of Sale

Consumers can buy raw juices in many different styles and sizes at many different types of establishments. Below we attempt to describe as many as possible:

1. Grocery Stores (produce-section-related juice). Juice is squeezed from fruit on the premises and sold in multi-serving-size containers or jugs.
2. Grocery Stores (refrigerated section). Juice is supplied by external raw juice processor in single or multi-serving-size container or jugs.
3. Roadside Stands. Juice is processed by the vendor and sold relatively near the originating orchard direct to the consumer in multi-serving-size containers. Samples are often given out in small disposable cups.
4. Farmer's Markets. Juice is processed by the vendor and sold relatively near the originating orchard direct to the consumer in multi-serving-size containers. Samples are often given out in small disposable cups.
5. Onsite. Juice is processed by the vendor and sold onsite at the originating orchard direct to the consumer in multi-serving-size containers. Samples are often given out and single servings sold in disposable cups.
6. Storefront Juice Bars. Juice is squeezed from fruit/vegetables on premises OR blended with externally supplied, bulk raw juices OR blended with raw juice concentrate and sold in single serving size, disposable cups; juice is typically not consumed in volume on the premises because the sound of the blenders is unpleasant.
7. In-Store Juice Bars. These bars typically exist inside a facility devoted to another activity, e.g. shopping mall, restaurants, grocery store or fitness facility. They have similar production processes and serving containers to Storefront Juice Bars. Juice is more often consumed on the premises because the loud blenders are used only intermittently.
8. Restaurants. Juice is squeezed from fruit/vegetables on premises OR blended with externally supplied bulk raw juices OR blended with raw juice concentrate and sold in a single serving size in a reusable glass.
9. Amateur Segment. Juice is processed by churches or schools as part of an event and sold by the disposable cup or a multi-serving-size container.

Thus, a significant percentage of raw juices may, in fact, be sold by the glass. To date, Jamba Juice, a California-based juice bar franchise, has 32 juice bars. In a February, 1997 New York Times article, Jamba Juice officials stated that their businesses grossed between $300,000 and $1,000,000 per storefront. If there were only 200 other juice bars (which is a low estimate) in the U.S., and they and Jamba Juice's stores averaged only $300,000 per store, the Juice Bar market alone would be worth $69,600,000.

Unfortunately, education efforts by the "juice" industry and government have alerted only a percentage of the juice producers closest to growing the fruit and not juice producers across the other segments listed above. S.T.O.P. believes that the farther away the processor gets from the raw fruit industry, the less aware they are likely to be of the potential problems for contamination in juice. As anecdotal information we offer a grocer indicating he would sell raw orange juice into an elementary school lunch program because "we squeeze it ourselves on site." It is quite possible that juicing equipment in stores is cleaned less frequently than the average apple press.

Because it does not address the "immediate consumption" segments, the FDA's Proposed Rule is creating an imbalance in the marketplace by requiring only the

"later-consumption" containers bare a label. As a result, we believe that all raw juice suppliers will feel pressured to sell their products into market segments where they are not required to label and where consumers will not receive proper warning. Juice bar suppliers specifically tout their concentrates which have "not been heat treated and therefore have superior flavor." FDA should not underestimate the size of businesses such as JR Woods (Atwater), VacuDry (Sebastapol), MetWest Agribusiness (Del Rey) in California which buy fruit and vegetables and supply juice or concentrates to retail storefronts. These same types of businesses can also be found in Florida and other states.

In Conclusion

An understanding of the total market size shows that the problems that have led FDA to take action are particularly urgent because the market is in all likelihood substantially larger than FDA had originally concluded. Different areas of the country are likely to see raw juices with a higher marketshare percentage than FDA presently suggests with its 98% figure, specifically, the North East, Florida and the West. Roadside stand sales are more likely to represent significant marketshare in New England, Florida, Washington, Oregon and California. Juice bars have proliferated in California and are likely to flourish in areas where coffee bars have become prevalent, and where weather supports interest in fruit juices and smoothie drinks for at least 2/3 of the year.