JUICE SAFETY COMMENTS

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RE: **Docket No. 97N-0511**
(Technical Meetings on Juice Safety/Juice HACCP)

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

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

Today, we are writing to comment on issues raised at two public meetings directed at minimally processed citrus juice producers in November 1998 that have a direct impact on the juice HACCP rule. S.T.O.P. strongly supports FDA's efforts to improve juice safety through juice labeling and juice HACCP.

Our comments today are organized as follows:

I. Executive Summary

- FDA needs a single table describing juice outbreaks in terms of their sources, causes, and the ages and severity of illnesses in the victims.
- New data from the Irvine meeting suggests FDA has underestimated the size of the retail market for unpasteurized juices; FDA should revise its target markets for the rule accordingly.
- New data from the Florida meeting suggests significant potential for contamination in small juice businesses; FDA should revise its target markets for the rule by including juice bars and conducting microbial inspections of juice processing conditions at juice bars, restaurants, and grocery stores
- FDA appears to have determined that a 5-log reduction is sufficient. S.T.O.P. disagrees based on several elements of the NACMCF recommendations that have not been adequately defined to ensure that juice is treated to remove pathogens to a level of safety. Data suggests that a 5-log reduction will not be sufficient for many children under the age of 1. Based on the latest data, FDA should reexamine the 5-log killstep in favor of a more prudent 6-log killstep
- S.T.O.P. believes that FDA must establish a set of prerequisite conditions which fruit must meet prior to being considered part of a reduction process in order to ensure consistency in the safety of minimally processed juice.
- Culling and grading should be considered part of the prerequisite conditions and specifically not part of the approved reduction methods.
- Multistep reduction methods are inherently less safe than a single killstep, all other things being equal, but especially under conditions where the steps are separated by vast time, temperature and location differences.
- FDA and industry appear to be establishing current citrus juice reduction standards based on the assumption that the interior of the fruit is sanitary. S.T.O.P. is concerned that science has recently shown that fruit can be contaminated through stem scars and that if the "sanitary interior" proved to not be true, many of the proposed multistep reductions would be insufficient to provide safe juice.
- S.T.O.P. urges FDA to support *E. coli* O157:H7 and *Listeria monocytogenes* as target organisms unless more resistant organisms are identified. FDA should set zero tolerance performance standards for these organisms. Testing for O157:H7 should be conducted with enrichment broths and the latest technologies as recent data from alfalfa sprout meetings is showing that organisms can be damaged and survive but not grow on commonly used selective media.
- FDA needs to build a basic "education" presentation into every meeting it holds with industry to explain the issues that have brought industry to this point. This will help ensure that producers understand FDA's motivations.

II. Background on Unpasteurized Juice Outbreaks and Contamination

S.T.O.P. would like to reiterate a point raised in our last comments that FDA should publish a list of outbreaks in a tablular format (please see our preferred, expanded example format in our Juice HACCP Comments, dated August 7, 1998). Data

included in this table should give a rough breakdown of ages of victims as well as the seriousness of their illnesses, along with the size of the producer involved and the implicated cause of the contamination. It should be verified by the CDC.

U.S. outbreaks and recalls related to fresh juice include:

Date	**Organism**	**Juice Type**	**States**	**Cases**
July, '89	*Salmonella*	Orange	NY	69
Oct., '89	Unknown	Orange	CO	22
Fall, '91	*E. coli* O157:H7	Apple	MA	23/4/0
Nov., '93	Unknown	Orange	OH	23
Oct., '93	*Cryptosporidium*	Apple	ME	213
May-June, '95	*Salmonella*	Orange	FL	60
Oct., '96	*E. coli* O157:H7	Apple	CT	10/2/0
Oct., '96	*Cryptosporidium*	Apple	NY	32
Oct., '96	*E. coli* O157:H7	Apple	WA	6
Aug.-Nov., '96	*E. coli* O157:H7	Apple	BC, WA, CO, CA	70/14/1
Oct., '97	*E. coli* O157:H7	Apple	MI	Recall

These outbreaks are all mentioned in a combination of the juice HACCP and juice labeling proposed regulations.

Numbers above with slashes indicate total cases, cases of HUS, and deaths in O157:H7 outbreaks for which the information is available. The U.S. data would be supplemented by international data, possibly in a separate chart, indicating for example that there have been at least two more outbreaks associated with apple cider in Canada, one of which was ongoing in November of 1998. Also of note, it was reported that Odwalla had found evidence of *Listeria monocytogene*s in its unpasteurized juices prior to the *E. col*i O157:H7 outbreak caused by that company**.**(1) Thus, identified contamination in citrus juice has not just been limited to *Cryptosporidium*, *Salmonella* and *E. coli* O157:H7.

However, outbreak and recall data alone do not convey the widespread nature of contamination in unpasteurized juice. An investigation of U.S. cider producers showed fecal-related contamination (fecal coliforms and generic *E. coli*) in 14% of finished product under tests conducted in 1997-1998.(2) In U.S.D.A. and Florida Department of Agriculture inspections, 4% of samples representing 5% of firms failed basic sanitation tests**.** (3) In short, contamination in unpasteurized juices is NOT a problem that has been resolved either in Florida or around the country. Therefore, consumers expect FDA to implement regulations that will introduce added safety to this market.

III. Flaws in FDA's Target Market Analysis

Relative sizes of various juicing businesses reported at the California and Florida meetings suggest FDA's economic analysis on the impact of juice hazards is flawed.

FDA's juice economic analysis provided initial estimates that only 70 million gallons of minimally processed juice were produced annually (98% of the market is pasteurized, according to many FDA documents) in the United States, and that 14 percent of minimally processed juice (10 million gallons) would be exempt from the HACCP rule but would be covered by the labeling rule. (4) FDA also estimated there are approximately 13,000 chain grocery stores of which it calculated 10% or 1,300 might be processing and selling packaged minimally processed juice.(5) It identified 34,100 independent grocery stores and supermarkets and calculated that 5% of these or 1,700 independent stores might be affected be affected by the rules because they would be producing minimally processed juic**e**. Thus, FDA's assessment was that 7 million gallons per year were produced by grocery stores, restaurants or juice bars ("independent stores").

At the Irvine citrus juice meeting, held by FDA in November of 1998, new data on the retail market was provided by Juice Tree Company,(6) which indicated that the top three manufacturers had sold "30,000 knife cutting juicers for small commercial juice situations around the country." These juicers can process 14 oranges per minute. From the transcripts, it is not entirely clear whether just one of the top three had sold 30,000 units or whether all of the top three manufacturers had sold 30,000 in total.

Assuming that there are "only" 30,000 units around the country, if each orange produces 2 ounces of juice, the machines would run at 28 ounces per minute or 1640 ounces (= 12+ gallons) per hour. If each store only runs its juicer for one hour per day every day of the year, 12 gallons per day * 365 days per year would yield 4380 gallons per machine. At 30,000 machines in distribution, the production of juice from small commercial juice situations around the country would be: 131,400,000 gallons per year. Even if we HALVE the amount of juice produced by these juicers because, for example, oranges actually only yield 1 ounce of juice or they only operate for a half hour, this small commercial juice production would be in excess of 65 million gallons, or almost equal to the entire production FDA has estimated for minimally processed juices.

According to Dr. Mohamed Ismail of the Florida Department of Citrus,(7) Florida divides its unpasteurized juice market into three segments. The first segment is the fresh fruit citrus industry which consists primarily of 100 packinghouses shipping fruit all over the world. These packinghouses also resell fruit to U.S. retail facilities that turn it into juice. A second segment is the gift fruit shipping industry which consists of "approximately 300 vendors ranging in size from a small one room store to large operations complete with packinghouse equipment and even candy manufacturing facilities and fresh juice extraction." According to the transcripts, "almost all" of these roadside vendors sell unpasteurized juice. The third and last segment is the large volume, unpasteurized juice producers. "Fresh juice is packaged in various size packages and shipped under refrigeration. Some of businesses also ship fresh squeezed juice in refrigerated tankers for packaging elsewhere." It would appear that the retailers buying from the packinghouses, and the gift fruit shipping industry may be representative of the types of businesses buying juicing equipment.

S.T.O.P. strongly advises FDA to reexamine its quantifications of the unpasteurized juice market in the light of the volume of juicing equipment distributed around the country. It is clear that the retail market, whether through grocery stores, restaurants, or other retail situations such as roadside gift fruit shipping businesses, has been grossly underestimated.

IV. Exclusion of Key Markets from The Rule

As S.T.O.P. has indicated in multiple sets of previously submitted comments, FDA's juice HACCP plan as initially proposed excludes key segments that represent a significant threat to public health.

Inspections conducted by the USDA and Florida Department of Agriculture reveal the following types of generic *E. coli* contamination:

"Out of the last couple of years in looking at 452 samples, or 300 individual firms, we have only found 20 samples that were positive for E. coli, which is roughly about 4 percent of the samples, or roughly about 5 percent of the firms. What type of firms were these E. coli detected in? Well, of these firms, 12 samples, or nine of the firms, were classified as gift fruit shippers, three of the firms were small markets, three firms or four positive samples were from retail chains, and one was from a small juice bar. If you break it down even further, you'll see that four of the gift fruit shipper firms could be classified as a small processor, where five firms were just, basically, what we classify as a gift fruit shipper, maybe a small stand**.**"(8)

To give you a better sense of these numbers, we present them in a table:

Type of Processor	Number with Contamination
Gift Fruit Shippers - Small Processor	4
Gift Fruit Shippers - Small stand?	5
Small markets	3
Retail chains	3
Small juice bars	1

In short, what USDA and the Florida Department of Agriculture found was at least 13/16 of contamination qualified as small business/retail outlets.

Once again, we point out that we have not seen FDA's internal report on unpasteurized apple cider inspections, mentioned in the final Juice Labeling Rule, but we believe that the 14% of contaminated samples identified may add additional data that supports the premise that small businesses, grocery stores and juice bars are as likely, if not MORE likely, to cause outbreaks as larger producers. In the above mentioned apple cider outbreaks and recalls, at least two outbreaks (CT, MA) and a recall (MI) were caused by small produce**rs.**

Based on analysis of 30,000 knife cutting juicers sold around the country, either the grocery store segment is dramatically larger than FDA has estimated OR juice bars and restaurants are considerably larger, but the fact stands that FDA has underestimated the amount of unpasteurized juice consumed through retail segments in the United States. Likewise, as many of these operate selling juice by the glass, the retail exemptions proposed will allow a significant percentage of these to operate without either HACCP OR a label. According to the economic analysis (page 24264), "FDA estimates that the exemption from the HACCP rule for retailers and small retail processors will affect 14 percent of the volume of unpasteurized juice." This estimate now appears to be just plain wron**g**.

It is imperative that small producers and retail outlets be included in the juice HACCP regulations in order to ensure the safety of juice in the United States. S.T.O.P. finds it inexcusable that FDA continues to ignore the juice bar market, and within that market, the wholesale of unpasteurized juices and purees to retail vendors. Similar to its investigation of cider producers, FDA needs to carry out an industry-wide investigation of juice processing sanitary conditions at juice bars, restaurants and grocery stores to justify that these juicing facilities do not deserve closer scrutiny.

V. De Facto Selection of 5-Log Killstep

Based on FDA's promotion of a 5-log killstep to industry at the citrus juice meetings, it appears that FDA has already concluded that a 5-log killstep is sufficient. S.T.O.P. has argued in previous documents that a 5-log killstep may not be sufficient and that a 6-log killstep would therefore be more appropriate. The selection of a 5-log killstep on the part of the NACMCF was based on several assumptions that FDA has not gone back to reexamine publicly. One of the NACMCF's conclusions was:

"The Committee believes that a tolerable level of risk may be achieve by requiring an intervention(s) that has been validated to achieve a cumulative 5 log reduction in the target pathogen(s) or a reduction in yearly risk of illness to less than 10-5, assuming consumption of 100 ml of juice daily."

Four critical factors are left out of this relatively simplistic conclusion***:***

1) Who are the at-risk consumers and do they drink 100 ml of juice daily?

S.T.O.P. points out that the target community that FDA seeks to protect with its ruling include the elderly, the immune impaired and children who need pathogen-free juice. In a letter from Roger Suchyta, Associate Executive Director of the American Academy of Pediatrics, to the FDA, dated 1/31/97, the AAP indicated that:

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

consumed at least 12 ounces a day with 15% consuming more than 15 ounces a day."

Note that the 100 ml daily consumption estimated by the NACMCF is roughly 3 ounces of juice. This survey data indicates that 20% of the most at-risk group *drinks more than* 5 times the NACMCF estimated amount of juice PER DAY. It would appear from the data as well that as babies transition from the first six months to the second six months of life, they consume more juice. These unlabeled products could still carry harmful bacteria that might be lifethreatening to children. Therefore, a 5-log reduction would be insufficient for this vulnerable at-risk group.

2) What is the anticipated pathogen load prior to measuring the reduction?

In its recommendations, the NACMCF also suggested that there was a need for "baseline studies in the incidence of human pathogens on fruits and vegetables, particularly those used in juice processing." (9) This research would be valuable to establish an anticipated microbial/pathogen load that would be going into the killstep or reduction process. Without a clear mandate by FDA disallowing the use of drop fruit and specifically requiring employment of other procedures we recommend below, it is completely unclear what the initial load on the fruit going into the process will be and therefore whether a 5-log killstep will suffice.

According to Dr. Martha Roberts, Deputy Commissioner for the Florida Department of Agriculture and Consumer Services,(10) in USDA and Florida Department of Agriculture inspections, of 452 samples of minimally processed citrus juice from 300 producers, 20 samples were found to be positive for generic *E. coli*. Of these samples, at least two had high microbial loads, and of these, at least one had microbial loads in EXCESS of the NACMCF assumption.(11) While we have not been given access to the FDA's study of cider producers, we suspect that FDA may have found greater levels of contamination in the fecally contaminated juice identified in 14% of finished cider products tested in 1997-1998(12) than have been found in Florida unpasteurized citrus juices. As FDA knows, the presence of fecal contamination is strongly linked to the presence of pathogens.

This data suggests that some juice producers presently use fruit or processing that is so unsanitary that a 5-log reduction may not ensure safe juice. Indeed, "juice" grade fruit is by definition fruit that has a lower overall caliber of quality than commercial grade fruit. While some of this fruit may merely be the wrong size, odd shapes, crevices, puckers and blemishes can make this type of fruit harder to sanitize. FDA needs to be sure that the microbial load going into the reduction process will not overwhelm the purpose of the reduction process and result in unsafe juice.

3) From which point is the 5-log reduction measured?

FDA has not established a clear "start point" from which point in the processing (from growing the fruit to packaging the juice) the 5-log reduction can begin to be measured. As a result, all reduction methods, no matter how filthy the initial fruit, are being included by producers as counting toward the cumulative reduction. One company can start measuring a 5-log reduction from when they pick the fruit up off the ground. Another company can be measuring its 5-log reduction after hand-picked fruit is transported under refrigerated conditions and then culled at the plant. Indeed, under the cumulative method, a cider producer could claim 1-3 logs of

reduction through culling, brushing and washing and then only need to conduct a 2 log heat step to claim a 5-log reduction. FDA must set a calibration point from which to measure the reduction.

4) What are the target pathogens?

Lastly, FDA has not clearly identified a target pathogen. At the Dec. 16-17, 1996 meetings, the issue of target organisms was also raised. There, the NACMCF had also concluded:

"In the absence of specific pathogen-product associations, the committee recommends the use of *Escherichia coli* O157:H7 or *Listeria monotcytogenes* as the target organisms, as appropriate."

FDA must select target pathogens that make scientific sense by choosing organisms that cover the extremes of pathogenic viability across multiple steps in a reduction method. At the November, 1998 citrus meetings it was disclosed that members of the citrus juice industry are us*ing Salmon*ella as their target organism*. Salmon*ella is NOT as acid resistant as *E. coli* O157:H7, which has a greater capacity to develop acid resistance. Thus, in methods of reduction which involve the use of acids, a citrus juice producer achieving a "5-log reduction" for *Salmonella* may only be a "4+ log reduction" for *E. coli* O157:H7 and will fail to provide the measure of safety required. Therefore, the use of *Salmonella* alone as a target organism for multistep reductions *using nonpasteurization techniques* does not suffice to provide safety from *E. coli* O157:H7.

It would also appear that *Salmonella* was selected by the participants because two outbreaks associated with unpasteurized citrus were caused by *Salmonella*. However, in an additional two citrus juice outbreaks, the pathogen was not identified. Therefore, the case for *Salmonella* as a target pathogen alone is not sound, and S.T.O.P. is opposed to i*t.*

E. coli O157:H7 is superior to *Salmonella* as a target organism because of its acid resistance; a few of the recommended reduction steps mentioned at the Florida and California meetings involve the use of modified pH*. Listeria* is generally considered more heat resistant than either *Salmonella* or *E. coli* O157:H7, and is also most resistant to environmental stresses such as sanitizer*s.*(13) *Listeria* was found in Odwalla brand juice by Odwalla quality assurance managers prior to the outbr**e**ak.(14) S.T.O.P. strongly supports the use of *E. coli* O157:H7 and *Listeria* as target pathogens for all unpasteurized juice reduction and killstep methods, unless more resistant pathogens are identified, and urges a zero tolerance standard.

Surrogates must accurately reflect these two organisms in terms of acid resistance, temperature resistance and the ability to form biofilms and develop greater resistance under repeated adverse conditions. Recent studies have shown that heating 0157:H7 without killing it leads to its developing greater heat resistance.(15) Research is needed to show that the same is not true of its ability to resist sanitizers or acids.

Given the number of potential quantifiable failings of a 5-log killstep under the current proposed regulation, S.T.O.P. continues to hold that a 6 log reduction would be more prudent**.**

VII. When is a 5-Log Killstep not a 5-Log Killstep?

There are several flaws in FDA's current support for multistep reduction processes for minimally processed fruit juices. One of the central purposes in establishing a safety performance criteria instead of mandating the use of a specific intervention technology such as pasteurization was to ensure that new technologies would continue to be explored and exploited for creating safer foods. Our understanding was that it was NOT established so that industry could cobble together Rube Goldberg solutions of technologies that might lend the appearance of sufficiency. However, this appears to have been the result.

A. Identify Pathogen Load and Starting Point of Reduction Measurement

Fundamental to the loopholes that FDA has allowed in its Proposed Rule is the fact that, while it allows each juice producer to come up with its own reduction process, FDA has not required that they all start with similar quality fruit.

As mentioned previously, the NACMCF left two critical elements of measuring a 5-log reduction as "an exercise for the reader":

- what did the NACMCF consider to be the initial pathogen load? and
- from what point should the reduction should be measured?

The NACMCF seemed to feel that a 5-log reduction would suffice to reduce organisms to an appropriate level; we can feel fairly confident that they therefore did not believe the juice processor would be starting with a pathogen load of 6 or 7 log organisms, all other measurements being equal.

Based on comments at the citrus meetings, members of the juice processing industry agree that the juice processor must start with what is essentially "clean" fruit. Dave Sperry of California Day Fresh, at the California meeting said, "You must have sound fruit to produce safe juice." Chuck Orman, also at the California meeting commented, "If you start off with a filthy piece of fruit, and you get a log-5, you still have a filthy piece of fruit." S.T.O.P. concurs wholeheartedly.

As described at the California meeting, the effectiveness of chlorine is adversely impacted if the fruit is dirty to begin with:

"Since chlorine is such a great oxidizer, binds not only to water as in the previous reaction, it also binds to dirt, leaves, oranges, whatever else is in the system. If the recirculating system is chlorinated and binds-- the chlorine binds to all the dirt that happens to be on the fruit, then you are using up all of your chlorine. Total chlorine is the sum of what's free and what's bound, bound to the dirt, bound to the bacteria, and therefore it is not useful at this time. So it is really important that we look at concentration of free chlorine, not just total." (16)

Using dirty, unculled fruit as the starting point of a reduction process virtually ensures that the organism load will be higher than that assumed by the NACMCF, it

casts doubt on the effectiveness of subsequent steps, and it suggests that the 5-log reduction can be overwhelmed.

FDA must set parameters by which all fruit juice processors will be starting their process measurements with at least comparable fruit. We would recommend the following.

1. All orchard fruit intended for minimally processed juice must be hand-picked from the tree, not picked up off the ground.
2. All fruit must then be hand culled for damage and blemishes such as crevices or dimples that might harbor microorganisms or make it challenging for sanitizers or brushes to reach.
3. All fruit must then be rinsed with pathogen-free water.

The latest research should be used to identify which rinsing methods results in the least cross contamination.

These three steps are simply gross filth reduction. They should not be considered part of the "5-log reduction" but calibrating measures that enable government to ensure that the fruit going into a juice process at a small roadside stand in Massachusetts is similar to the fruit being processed by a gift fruit shipper in Florida which should be similar to the fruit being processed by a large, minimally processed juice processor in California.

If FDA has difficulty understanding how to enforce this standard, S.T.O.P. would suggest that a new "grade" of fruit ("minimally processed juice grade" fruit) which would be subject to the above steps. Only this grade of fruit could be used in minimally processed fruit juices.

To allow any given producer to use anything other than visibly clean, unblemished fruit is to allow for great variation in the definition of a 5-log killstep... a variation which will virtually ensure that unsafe juice is being sold to consumers without warning label***s.***

B. Culling/Grading Should Not Be Considered A Reduction Step

If in the final juice HACCP rule, FDA fails to identify an appropriate starting point and pathogen load for minimally processing juice, it should not allow culling and grading to be considered as part of the cumulative 5-log reduction.

The U.S.D.A. definition of cider grade apples is:

"apples which are free from decay, worm holes and internal breakd**o**wn" (17)

Implicit in this definition of "juice grade" apples is that they have failed to qualify for the more stringent requirements of Grade Numbers 1 and 2, which are:

"....not overripe, which are free from decay, worm holes, freezing injury and internal breakdown and free from any other defect, or combination of defects..."

"Culls" are then defined as:

"apples which fail to meet the requirements of U.S. Cider Grade."

In any given harvest, fruit that meets commercial grade qualifications (size, shape, undamaged) is sold as whole fruit. The remaining edible fruit is qualified as "juice grade," and the rest is considered "culls." The technique of culling a batch of apples that fails to meet grades one and two thus has two purposes: 1) to identify and separate fruit with unusual cosmetic or shape characteristics, and 2) to identify and remove decayed, bruised or damaged fruit from a batch.

While culling and grading technically fit FDA's definition of a reduction method (because the definition is so loose), they are inappropriate to be included as part of the cumulative 5-log reduction to produce safe, minimally processed juice. The latest science has shown that microbes can more easily penetrate and adhere to broken or damaged cells on produce. Thus, culling merely removes from the juicing process fruit that should have been considered unsafe in the first place. Such fruit should automatically be presumed to harbor significant loads of potentially pathogenic microorganisms.

While culling may remove the larger percentage of obvious contamination, significant invisible contamination, even greater than the 5-log load, may remain because microbiological contamination is not limited to fruit that have been damaged or has crevices or blemishes. At the Florida meeting, Dr. Strobos pointed out that "When you have fecal contamination, the level of pathogenic organisms that you get in a fecal contaminant is usually in the 10 to 11 or 10 to 12 range." Thus culling/grading should merely be considered a pre-step that reduces the initial pathogen load from 10 logs to something closer to 7 or 6 logs.

Lastly, it is absolutely critical that FDA specify that loads of fruit that arrive with debris or dirt be culled first and then rinsed off prior to being placed in any dunk tank of flume that could carry contamination from unsanitary fruit with a high pathogen loads to relatively sanitary fruit within a batch. The practice of cross contaminating fruit bound for minimally processed juice by floating it in large tanks of water without adequate sanitizer must stop. FDA must stipulate that sanitizers employed in a reduction method should only be used on visibly clean fruit so that the true effectiveness of the sanitizer is employed.

C. A Single 5-Log Killstep is Not Equal to a Cumulative 5-Log Reduction Method

At the California meeting, FDA's John Kvenberg is quoted as saying:

"Everything we have done today assumes we are in a sanitary operation and nobody is introducing new bugs into this, because we are talking about the bugs that come in with the fruit. We are not talking about bugs that get on the fruit from an unsanitary plant. So we are talking about sanitary operations here."

Unfortunately, multiple participants at both meeting were specifically not speaking about this type of situation. A single 5-log killstep, such as pasteurization immediately prior to placement in sterile packaging is distinctly different from the many multiple step reduction methods proposed for citrus juices.

First, in the 5-log pasteurization for juice, putting all the juice of the apples together into a single batch creates a greater level of homogenization PRIOR to the 5-log killstep. While organisms are not distributed evenly throughout the batch, they are more highly distributed than the organisms on a single piece of contaminated fruit going through a per-fruit, multistep reduction process. Thus, the multistep reduction method is more easily overwhelmed by a high point load, i.e. a single piece of heavily contaminated fruit, than a single killstep operating across an entire batch of fl*u*id.

Second, more than one speaker pointed out that you cannot simply add killsteps cumulatively because two similar (brushing, for example) steps which each achieve a 1 log killstep independently will not achieve a 2 log killstep together because the first step would already eliminate most of the organisms affected by the second step.

Not mentioned, however, was that when FDA accepts using multiple steps in lieu of a single step, it accepts the potential for added contamination between steps. The fact that additional control points are being introduced increases the overall estimated risk of the system. In point of fact, we are NOT concerned simply with contamination that might come in on the fruit, but also about contamination that can occur in plant, in handling, or in transport. Handler errors have played a significant role in citrus juice outbreaks. It is a luxury to presume that all steps are completely sanitary; the chances of each step going wrong in an open system are multiplied across the additional steps to create a combined risk assessment. Thus, a third argument against equivalency between pasteurization and a multistep 5-log reduction is the increased risk inherent in a multistep system.

Fourth, while we believe that FDA might be able to make an argument that *in a sanitary plant*, fruit handled in a multistep reduction method to produce minimally processed juice might be able to achieve something close to a 5-log killstep, we refuse to accept this argument when significant time and temperature variations are introduced between steps. Washing in the field followed by waxing at a gift shipper followed by juicing at a grocery store fails to meet the 5-log criteria by introducing many potential points of contamination and opportunities for *growth* of organisms between steps. Indeed, unless fruit is shipped under refrigerated, dry (not humid), truly sterile conditions, we contend that any new or remaining contamination could easily grow back before the fruit is squeezed. This type of reduction simply cannot be considered equivalent to a system that is entirely in-plant and, especially not to an in-plant process that includes pasteurization conducted under sanitary, HACCP principles.

FDA must bring to an end the illusion that any sequence of different reduction steps will meet its criteria. While the simplest and most scientifically exact way to achieve this would be to disallow multistep reduction methods, we do not believe that FDA will take this step having already committed to industry that this approach will qualify. However, we do expect FDA to take a strong stand against reduction steps separated by vast physical, time and temperature parameters. If multistep reductions are to be allowed, either they must be carried out under stringent sanitary conditions followed by FDA oversight or the level of reduction achieved must be significantly higher.

D. Assumption that the Interior of Citrus Fruit is Sanitary

A major difference between pasteurization of apple juice, for example, and the multistep reductions proposed for citrus juices is that pasteurization will treat the juice itself from the fruit, whereas in the citrus juice reduction steps, the citrus juice is left relatively untreated. This has been deemed adequate from a hypothesis that citrus juice is naturally sterile.

Science is now proving that different types of produce can uptake pathogenic organisms through their stems. The tomato stem scar, in particular, has been the focus of this type of research and has led to a requirement that when tomatoes are placed in dunk tanks there must be a temperature differential between the tomato and the water to help ensure that the interior of the tomato does not become contamin**a**ted.(18) If it were possible for the stem scar of a citrus fruit to uptake pathogens, when it was dumped into a rinsing tank, for example, it would be possible to contaminate the interior juice of the fruit, rendering a multistep reduction process that addresses the exterior of the fruit insufficient to provide safe juice.

S.T.O.P. merely points out that all the science supporting a sterile interior of citrus fruit may not be complet**e.**

VII. End Product Testing Requirements

S.T.O.P. strongly believes that end product testing must be conducted, especially for multistep reduction processes. Fecal coliform testing alone, while helpful as an indicator, is insufficient because of the heartiness of *E. coli* O157:H7 and its ability to resist acid treatments in particular. S.T.O.P. expects FDA to develop a performance standard of zero tolerance for *E. coli* O157:H7 and *Listeria*. Microbial testing for *E. coli* O157:H7 should be conducted using the latest technology available in combination with enrichment broths and NOT on McConkey Sorbitol agar alone. Testing for *E. coli* O157:H7 in alfalfa sprout seeds has shown that injured *E. coli* O157:H7 organisms do not necessarily grow out on McConkey Sorbitol but are, in fact, present after the heavy use of sanitizers**. (19)**

VIII. Motivating Industry: Current Education Efforts Toward Juice Producers are Inadequate

The transcripts from the November meetings indicate that FDA unfortunately lost a significant opportunity to educate industry about foodborne illness by skipping over the "whys" and going straight to the "hows." From the transcripts, it is apparent that some people attending these meetings were not aware of the Agency's rule rationale. While the citrus juice meetings in Florida and California took place after the label rulemaking already occurred, it is important to provide very basic information about issues of food safety at such venues in order to ensure that industry understands the breadth and depth of the public health issues caused by juice contamination. The type of information industry needs to know includes:

- a basic understanding of the emergence of pathogens in recent years
- number of children, immune impaired, seniors affected

- severity of illness and its long term repercussions
- basis for underreporting of all foodborne illnesses around the country
- potential sources of different outbreaks

Some of the quantification could be handled by the table recommended in section II.

By failing to repeatedly quantify and qualify public health issues to members of industry, FDA continues to leave industry with the impression that the agency is acting arbitrarily and, to quote one Florida citrus producer, "And for all of these years and just to have an incident or two ruin it for people is -- is awful, terrible." FDA has an obligation to empower industry to proceed, not just out of fear of regulation, but out of an understanding of the magnitude of the public health threat of pathogenic contamination and the long term consequences for victims.

At the very least, information on Florida's 4-5% levels of fecal contamination in unpasteurized citrus juice was not subsequently distributed at the citrus meeting in California, though it would have been valuable.

As part of its overall communication strategy, FDA should develop a single presentation that provides the most basic data about organisms, the diseases they cause, outbreaks, the sources of outbreaks, and impact of such outbreaks pertinent to the industry with which FDA is dealing. While time is always short, it is imperative that FDA continue to reiterate the issues that have brought the agency to this point so that juice producers do not walk away with the impression that it is a "mere incident or two" that has caused regulations to be put into pla**ce.**

VII. In Conclusion

FDA's citrus juice meetings, while well intentioned, have pointed out how woefully inadequate the Proposed Rule for Juice HACCP is. In proposing a performance criteria in place of a single, specific intervention technology, FDA has opened a Pandora's box of potential methods that has led industry to jump through hoops like a trained dog. In a few instances, highly committed, larger producers appear to have applied HACCP and science to achieve something similar to pasteurization. Unfortunately for consumers, the rest of the industry seems to be holding its breath, knowing that FDA:

- has not applied rules to the potentially hazardous members of the juicing industry,
- has not accurately assessed the full range of process risks, and
- will not inspect all producers to ensure that proper steps have been taken.

Equating the safety of a citrus juice that has been *heat treated*

- to a specific time and temperature criteria
- under sterile/HACCP conditions in a single plant
- following culling, brushing and washing

to a citrus juice that has been *multistep reduced*

- by multiple companies
- with transportation between them

is to put children, seniors, the immune impaired and pregnant women at risk. FDA must set basic calibration standards to ensure that all industry players are starting from the same point. If FDA continues to support multistep reductions, it must set a performance standard that is truly equal in risk/benefits to a single killstep. Lastly, FDA must mandate end product testing and zero tolerance for *E. coli* O157:H*7* and *Listeria monocytogenes*. Without these basic requirements, the 5-log requirement is meaningless. Garbage in begets garbage out. We look to FDA to create a rule that will dramatically improve the safety of all juices that are considered "minimally processed."

Nancy Donley,
President

Laurie Girand
Advisory Board Member

1. Carey, Pete, "Testing Dispute Preceded Tainted Odwalla Juice; Management Divided: The Quality Control Manager Disagreed with Newly Hired Superiors Over Testing Procedures and Unrelated Bacteria. Replaced as Quality Official, she later was contacted by FDA," 10/31/97.
2. Food Labeling: Warning and Notice Statement: Labeling of Juice Products; Final Rule; Federal Register: July 8, 1998 (Volume 63, Number 130), Pages 37029-37056.
3. Transcript of Proceedings, FDA Technical Workshop,; Citrus Research and Education Center, University of Florida, Lake Alfred, Florida, November, 12, 1998; page 34.
4. Federal Register, Vol., 63, Friday, May 1, 1998; page 24268
5. *Ibid.,* page 24273.
6. Transcript of Proceedings, Citrus Juice Workshop, Irvine, CA; November 19, 1998.
7. Transcript of Proceedings, Florida; *Ibid.,* page 39.
8. *Ibid.*, pages 34-35.
9. Recommendations of the Fresh Produce Subcommittee of the NACMCF per juice safety. No date.
10. Transcript of Proceedings, *Ibid.* , page 34.
11. *Ibid.*
12. Juice Labeling Final Rule
13. Conversation with Dane Bernard, Senior Director, Food Safety Programs, National Food Processors Association.
14. Carey, Pete, "Testing Dispute Preceded Tainted Odwalla Juice...," *Ibid.*

15. Summary from the National Meat Association, 7/6/98: "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. Researchers pointed out that the 160 F cooking temperature should be sufficient to kill even the heat-resistant bacteria."
16. Comments of Linda Frelke, Odwalla, Transcript of Proceedings, Citrus Juice Workshop, Irvine, CA; November 19, 1998.
17. "United States Standards for Grades of Apples for Processing," U.S.D.A., 6/1/61, reprinted 1/97
18. "Equivalency is 'two-way street,' Buchanan cautions fresh produce meeting," Food Chemical News, May 18, 1998, page 15.
19. FDA Sponsored Sprout Safety Meeting, 9/28-9/29/98, Washington, DC.; data by Dr. Beuchat, Atlanta, GA.