

NOTICE OF INTENT COMMENTS September 11, 1997

Date: September 11, 1997

TO:

Dockets Management Branch (HFA-305)
Food and Drug Administration
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FROM:

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Rick Kimes of Kimes Cider Mill in Bendersville, Pa., said he had no intention of adding warning labels... He recently took steps to ensure "dropped" apples, considered a risk for E. coli contamination when they fall off trees, aren't used in his cider.

-- "FDA To Seek Juice Warning Labels," Associated Press, 8/27/97

"Why stir up a storm when it has been pretty quiet?" asked Bill Aeppler of Oconomowoc, Wis., who sold 80,000 gallons of unpasteurized cider last year. ``Many (consumers) don't even know what coli is."

-- "FDA To Seek Juice Warning Labels," Associated Press, 8/27/97

One juicemaker is Clark, New Jersey-based, Fresh Juice Co., which markets frozen ``fresh squeezed" juices, some of which are not pasteurized. ``The key with natural juices is cleanliness at the processing centers and temperatures below 35 degrees" to prevent bacteria problems, said Al Rountree, director of national account sales at Fresh Juice. The company has a strict temperature control policy that prevents bacterium problems, Rountree said.

-- "FDA Announces Food Safety Measures for Juices," Bloomberg News, 8/27/97

"They want the labels to warn that the juice may contain bacteria. I guarantee that there's bacteria in juice. There's bacteria in your drinking water," said Mitch Gidzich, whose Gidzich Ranch in Pajaro Valley bottles and ships about 1,000 gallons of apple juice a week. He said that most bacteria are not harmful and do not pose health risks.

-- "FDA seeks warnings on unpasteurized juice," San Jose Mercury News, 8/27/97

"You love apple cider -- that delicious, full-bodied beverage with that unmistakable caramel color. Cider has been enjoyed by Americans beginning with this country's first settlers, when cider was a staple of the colonial diet. And fresh apple cider fits right into today's healthy lifestyles, because it is 100% fruit juice, sweetened only by

Mother Nature, and is fat-free and cholesterol-free. Outbreaks of E. coli O157:H7 infection due to contaminated fresh (that is, unpasteurized) apple cider have been far fewer than those due to some other foods. Healthy adults don't usually experience severe effects. However, children, the elderly, and persons with weakened immune systems are at greater risk of complications from illness caused by this bacteria. These persons should take precautions to protect themselves from foods that might carry this bacteria."

-- Consumer Cider Brochure, US Apple Association, September 1997.

In the wake of the FDA Notice of Intent, these quotes from apple cider producers and an industry organization show that mandatory FDA requirements are fundamentally necessary to protect consumers from repeated outbreaks. They underscore several key points:

1. Some members of industry, when asked to voluntarily comply with FDA's advice, will not follow it.
2. Some members of industry continue to believe that grounders and unpotable water are the ways in which their product can become contaminated. By eliminating these practices, industry members believe they have done all that is needed to make their products are safer.
3. Some members of industry continue to believe that FDA is making a "big deal" out of contamination; and that consumers do not need to be informed of risks. They specifically downplay the risks.
4. Some members of industry do not understand the life threatening nature of E. coli bacteria, killsteps or the science of the conditions under which bacteria survive.
5. Some members of industry will continue to market raw apple juice as a "health" related product.

To this, we would add a personal note. On September 9, a S.T.O.P. parent went to the local Whole Foods Market to ask about the ingredients planned for Whole Foods' catering of hot lunches at a nursery school. When specifically asked which fruit juices would be included, the manager replied that it would be pasteurized apple juice, "of course," and fresh orange juice. "We make the orange juice here," he said, implying that raw orange juice made at a grocery store would be safer than that supplied from elsewhere.

In short, as retailers and the raw juice industry scramble to explain their understanding of raw juice contamination, at-risk consumers continue to be either uninformed or misinformed.

We therefore would like to remind FDA and OMB that:

· The primary consumers of apple juice are children

Unlike the majority of other foods handled by FDA, apple juice is consumed by children, and E. coli O157:H7 is deadly to children. Thus, raw apple juice is a product that is consumed by a target market for which it is most harmful. Until industry

practices change substantially, miscommunication of the key message or allowing the message to get lost will result in further illnesses and death amongst *children*. Children should not have to pay for our inability to change an industry overnight.

· *Raw juices are heavily marketed as "better for you"*

The raw juice industry has a significant financial investment in maintaining the impression that these products both taste better and are "healthier"--this is why their products often command a premium. In point of fact, executives of fresh juice companies will publicly state that raw juices contain enzymes, proteins and other organic compounds that are better for people, despite virtually no scientific evidence to support the statement. S.T.O.P. would conclude that convincing the raw juice companies to "educate" consumers about their products would not be successful.

· *Consumer education by routes other than labeling will be laborious and time consuming*

Unless the message is always made available at the point of purchase, it is quite likely to be lost in the noise and to incompletely cover the target audiences.

· *Consumers do not understand the level of harm these microorganisms cause*

During the 1930's, milk trucks in Sacramento, CA were known as the "White Wagons of Death" because of contamination. Unfortunately, decades of consistent pasteurization of milk have allowed a generation to grow up without direct exposure to life-threatening illnesses in unpasteurized products. As FDA knows, these microorganisms have only just emerged and there has been no consistent awareness or education campaign about the nature of these pathogens.

· *Consumers therefore do not understand the "benefits" of pasteurization*

For the labels "pasteurized" and "unpasteurized" to be effective without further wording, the consumer would need to know:

1. pasteurization is a heat treatment to a certain temperature and of a certain duration
2. such heat treatment kills bacterial and viral microorganisms, but not necessarily mold/fungal spores
3. the organisms that are killed in some cases could be life-threatening to certain consumers.

The consuming public does not fully understand all three of these components; therefore, using such definitions alone is insufficient.

Given the current circumstances, S.T.O.P. supports the general directions stated by the Notice of Intent. There are two key ways in which they fall short. The first is that labeling should have been mandatory in 1997, and the second is the timing of the announcement, which was very late.

Timing

We would like it noted at OMB that the timing of regulations and notices related to fresh produce and fresh produce products is **absolutely critical**. Unlike the meat industry which tends to sell product all year around, fresh produce and fresh produce products such as raw apple juice have a seasonality. That seasonality means that if government does not act substantially prior to a season, at-risk consumers are left particularly at risk for that season during the year. The bureaucratic back-and-forth that leads to lengthy delays on these types of rulings is completely unacceptable. We hope that the government will recognize that the failure to deliver this Notice of Intent in a timely fashion was an injustice to both industry and consumers and will take action to ensure that this is not repeated as FDA goes on to handle other fresh produce and fresh produce product industries.

Labeling

With regards to the specifics of the Notice of Intent, S.T.O.P. supports the position that unpasteurized, raw juices should be labeled and because we believe that voluntarily labeling will result in imperfect coverage, S.T.O.P. believes warning labels should be mandatory. We support all four elements of the potential warning label. The word "WARNING" or something similar to it is absolutely critical; otherwise, the message may be lost in the rest of the packaging. We also support FDA's instruction that pasteurized juice manufacturers carry a label stating that their products are pasteurized. Creating clear differentiations between the raw and unpasteurized products is critical to saving the lives of at-risk consumers.

HACCP

S.T.O.P. supports FDA's consideration of mandatory HACCP. Again, voluntary efforts are unlikely to have complete compliance and therefore the minimum safety quality in the industry will stay the same under a voluntary plan. Should pasteurization not be mandated, FDA will need to increase its inspections and monitoring of juice manufacturers. However, as we have learned in other areas, government agencies are already stretched thin in terms of inspection resources; we would ask that the Secretary of HHS appeal to Congress to increase their funding for this purpose.

Key elements of a juice HACCP plan S.T.O.P. would expect to see would include:

- detailed requirements back to the orchard or farm restricting contact with animals, animal feces, insects, dust, people, and unpotable water;
- testing specifically for E. coli O157:H7 and salmonella;
- frequent monitoring for compliance.

A HACCP plan is only as good as the support it receives from management and workers. We would expect a phase-in approach to take no more than two years.

Education

S.T.O.P. looks forward to more details on consumer education plans. The initial proposals appear to be a small step forward. S.T.O.P. would like to understand specifically,

- exactly how many people will be involved in outbound consumer education programs IN SEPTEMBER?
- how many hours of their time will be spent on the issue of juice safety?
- how much time will be spent with industry vs. consumers?
- how much money will be spent on which programs?
- what alliances will be formed with the target audiences?

Some or All Raw Fruit Juice?

As to the question of which raw juices should be included, S.T.O.P. supports the position that **all** juices should fall under these regulations. If a juice is not pasteurized, a HACCP plan and mandatory warning labels should be required. It is our impression that one of the reasons raw apple juice has become the poster child for juice safety is because so many children drink apple juice that outbreaks related to it are more easily identified... statistically, the development of HUS in *children* is one of the indicators epidemiologists seek. However, government's failure to identify other juice outbreaks should *not* be construed as an indication that other raw juices are not related to outbreaks. Until parents clearly hear the message that raw juices pose a risk to small children, uninformed parents will continue to feed such juices to their children, naively confusing "freshness" with "health" without regards to contamination. In the interest of their personal safety, consumers deserve to have the same information that industry and government have in order to make informed choices about the safety of the food they consume.

Laurie Girand

Board Member

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