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Newscast: US government issues new rules designed to crack down on dangerous juice products

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04/21/1998

CBS Evening News

CBS, Inc.

Burrelle's Information Services

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DAN RATHER, anchor:

Three major stories tonight affecting your life on the road, your access to the information superhighway and what's on your dinner table. First, about the risk in the food chain. The US government today issued new rules designed to crack down on dangerous juice products that can make you sick or even kill. CBS' Eric Engberg has our report on that.

ERIC ENGBERG reporting:

Only 2 percent of fruit and vegetable juices have not gone through pasteurization, the heating process that kills germs. But the Food and Drug Administration has worried about that 2 percent ever since a 1996 E. coli outbreak traced to apple juice killed an infant and made 66 others ill. The agency is proposing new rules that would require fresh juice processors to make sure the product is safe from E. coli and salmonella. To get bacteria counts down to the same level as pasteurized products, non-pasteurizing producers will have to adopt techniques such as washing or scrubbing the fruits and vegetables or using anti-microbial solutions. Consumer groups said the regulations are overdue and needed.

Ms. CAROLINE SMITH DEWAAL (Consumer Advocate): The bacteria have changed, and they've become more common in these products, and so the juice producers have to change, too.

ENGBERG: If the new regulations are approved, makers of non-pasteurized juices will have to put a warning label on the container which states, 'This product has not been pasteurized and, therefore, may contain harmful bacteria which can cause serious

Source: CBS Evening News, April 21, 1998

illness.' Large manufacturers will have one year to post the warnings, small firms two years and very small firms three years.

The new rules would apply only to bottled or packaged juices. Places where the juice is consumed on the premises, everything from bars to restaurants to kids' lemonade stands, are not covered by the new regulations. Eric Engberg, CBS News, Washington.
Program Time: 6:30-7:00 PM
Nielson Rating 10452720
Reference: 980421

FDA to Propose Juice Safety Regulations

Aim Is to Prevent Contamination; Some Products Would Get Warning Labels

By JOHN F. HARRIS
Washington Post Staff Writer

The Clinton administration this week will announce new regulations designed to improve the safety of juices, in particular fresh-squeezed varieties such as the bacteria-tainted apple juice that caused one death and widespread illness in western states in 1996.

While many consumers buy expensive fresh-squeezed juices on the belief that they are more healthful, food safety experts say the opposite often is true if these juices have not been pasteurized or undergone other procedures to kill disease-causing organisms.

The Food and Drug Administration this week will seek public comment on proposed new rules that would require nearly all juice-makers to implement these procedures, administration officials said. In the interim, the agency intends to require warning labels on unpasteurized juices to alert consumers that the products can contain hazardous bacteria and pose a special danger to children, the elderly or people with suppressed immune systems.

Contaminated juices are not a widespread public health problem. The vast majority of juices—some 98 percent—on the market are already pasteurized, regardless of whether they are fresh or made from concentrate, according to government and industry officials.

Even so, in recent years considerable attention has focused on the 2 percent that is not treated. In perhaps the most notori-

ous episode, a 16-month-old Colorado girl died and some 70 other people in Washington and other states became severely ill in 1996 by drinking Odwalla brand apple juice.

The juice had become infected with an especially toxic strain of *E. coli* bacteria, causing kidney failure and heart damage in the girl, Anna Gimmetad of Evans, Colo.

Under the proposed FDA rules, recently endorsed by senior White House officials, all juice producers would be required to set up procedures to prove to inspectors that they are monitoring health concerns and have sharply reduced the level of microbes that typically are found in untreated juice.

Administration officials said those juice bottlers who already pasteurize their products would most likely have little trouble meeting the new standards, although they must also demonstrate that they are monitoring for pesticide residue and glass shards in their products.

The new regulations also would allow for exceptions. Stores that sell juice for drinking on the premises, such as juice bars, would not be affected. Grocery stores and other retail outlets that press their own juice for sale on the premises but not for broader distribution would not have to pasteurize, but their products would have to carry the warning labels.

President Clinton has put an emphasis on food safety issues over the past two years, beginning in the 1996 campaign when he and his political advisers were

searching for issues that resonated with average voters and were looking for ways to counter conservative claims that the federal government should be scaled back sharply.

The new juice safety procedures mirror those already put in place by the FDA for seafood, which is also under that agency's jurisdiction.

The Agriculture Department, which regulates beef and poultry, last year announced new rules designed to reduce contaminated meat.

The new regulations, after being published in the Federal Register, may be revised after a public comment period, but administration officials said they expect them to be in place by the summer.

Gene Grabowski, a spokesman for the Grocery Manufacturers of America, said his organization's members would be looking closely at the details, but he predicted little opposition since most juice producers already pasteurize their products.

Caroline Smith Dewall, director of food safety for the Center for Science in the Public Interest, said the new rules are "critically needed."

The assumption until not long ago, she said, was that juices were acidic enough to prevent bacteria from growing. The Odwalla case and others like it in recent years have shown this is not the case.

Without the new rules, she said, "we'll reach the point where we'll have to keep children and elderly from drinking cider."

Monday, April 20, 1998
The Washington Post

Safety legislation spurs food fight

U.S. growers worry bill may limit exports

By George Rainie,
SAN FRANCISCO EXAMINER

The blessings of the global food market are many: There's summer squash in the chill of winter and winter squash in the heat of summer, and no end to peaches, nectarines and apricots. Those tomatoes in your salad are most likely from Mexico. New Zealand apples are just arriving.

There's another blessing: Our food is almost always safe. That's certainly true for the 34 million tons of fruit and vegetables — one-half the nation's yield — produced annually in California, where the world's highest food safety standards are imposed.

But now a one-page piece of legislation pending in Congress with the seemingly laudable purpose of helping ensure the safety of food imports is causing a rumpus.

The big guns of the agricultural trade associations nationwide have in their sights a bill that would authorize U.S. Food and Drug Administration inspectors to halt imports of fruits, vegetables or other foods from foreign countries whose food safety standards are not on par with those of the United States.

They protest that the bill sponsored by Rep. Anna G. Eshoo, California Democrat, establishes a trade conflict that will lead foreign inspectors to reciprocate by passing judgment on U.S. foods. At worst, opponents say, the bill could draw retaliatory restrictions on portions of the nation's food exports.

As the nation's leading agricultural exporter, California has the most at stake. Of a total of \$12 billion in state exports in 1995, \$3.4 billion was in fruits, vegetables and nuts, most of it sent to Asia.

"This is a diplomatic nightmare," said Jasper Hempel, vice president of the Western Growers Association, an agricultural trade organization of 3,400 growers, packers, shippers and processors of fruits, vegetables and nuts in California and Arizona. "It would create an unnecessary tension between the United States and our trading partners," he said.

The U.S. Department of Agriculture

already has the authority abroad to inspect and, if necessary, block the import of potentially unsafe meat and poultry. Miss Eshoo seeks to expand jurisdiction over fruits and vegetables.

"This is a kitchen table issue for the American people," said Miss Eshoo. "I think one of the great, great blessings of this country is the public health standard that we do have. Now, in a shrinking world, one of the first measurements of a growing country is what kind of public health standards they have, and by this [legislation] we can help our neighbors."

She pointed to several outbreaks of food-borne illness that she said give her legislation urgency.

Notably, the parasite *cyclospora* sickened 2,000 Americans who ate Guatemalan raspberries in the spring of 1997. There has also been cholera from frozen coconut milk processed in Thailand, *cyclospora* infection from lettuce grown in Peru and an outbreak of hepatitis A associated with frozen strawberries from Mexico.

Critics note that contamination is more readily traced to the kitchen than to farms.

"It's people leaving milk out, people leaving mayonnaise out, leaving prepared foods out of the refrigerator. The answer is with consumer education," Mr. Hempel said.

While microorganisms found on fruits and vegetables have been associated with food-borne outbreaks, critics say, these outbreaks are most often due to cross-contamination, or the transfer of microorganisms — from an uncooked hamburger to a carrot being chopped on the same cutting board, for example.

Since 1996, the Centers for Disease Control and Prevention has reported 3,277 food-borne disease outbreaks. Of these, fresh produce was linked to 21 outbreaks, 10 of which were the result of cross-contamination during food preparation. In all, 97 percent of traceable food-borne disease outbreaks resulted from improper food handling and cross-contamination, the CDC said.

• Distributed by Scripps Howard.

The Washington Times

MONDAY, APRIL 20, 1998

FDA to Propose Steps To Improve Safety Of Fresh Fruit Juices

By a WALL STREET JOURNAL Staff Reporter

WASHINGTON — The Food and Drug Administration will propose new regulations this week aimed at improving the safety of fresh fruit juices, particularly those made by small companies and roadside orchards.

About 98% of fruit juices are pasteurized and aren't harmful to consumers. In 1996, some Odwalla brand apple juice contaminated with the bacteria *E. coli* 0157:H7 caused illnesses and one death.

Under the new rules, manufacturers would be required to monitor the production process more closely. In addition, juices that aren't pasteurized will have to carry a label saying they could be harmful to children, the elderly and people with weak immune systems.

But some groups, such as the National Food Processors Association, are calling for even stronger action. Allen Matthys, an association vice president, said the FDA should mandate that all juices be pasteurized or otherwise treated for safety.

"Heat treatment of juice destroys *E. coli* 0157:H7 and other pathogenic microorganisms of public-health concern," he said. "Juice or juice ingredients should receive heat pasteurization or an equivalent process sufficient to render these products free of dangerous microorganisms."

THE WALL STREET JOURNAL

TUESDAY, APRIL 21, 1998

National News Briefs

Warning Label Proposed For Unpasteurized Juice

WASHINGTON, April 21 (AP) — The Food and Drug Administration today proposed requiring warning labels on juice that has not been treated to kill disease-causing microbes. Processors would also be required to take new steps against contamination.

Although 98 percent of juice sold in the United States is treated to kill pathogens, the Food and Drug Administration estimated that up to 48,000 people were sickened each year by microbes like salmonella in untreated orange juice and E. coli in apple cider and juice.

In 1996, at least 66 people were sickened in the western United States and Canada from drinking untreated Odwalla brand apple juice tainted with E. coli. A 16-month-old Colorado girl died.

The label, which the agency hopes to make final by the fall apple harvest, would state that the product "may contain harmful bacteria which can cause serious illness in children, the elderly, and persons with weakened immune systems."

Official Recommends Overturning Union Vote

KANNAPOLIS, N.C., April 21 (AP) — A hearing officer for the National Labor Relations Board has recommended overturning the results of an election last year in which employees of Fieldcrest Cannon narrowly voted against joining a union.

The election last August was the

fourth time the Union of Needletrades, Industrial and Textile Employees had tried and failed to organize workers at six of the towel and bed-linen manufacturer's plants in Cabarrus and Rowan counties.

In a 72-page report received over the weekend by the union, the hearing officer, Randall Malloy, upheld the union's charges that the company engaged in surveillance of employees who attended union meetings during last year's election.

If another vote is held, it will take place under new management. Fieldcrest Cannon was bought by Pillowtex of Dallas soon after the election.

If the ruling is not appealed by next Wednesday, the full labor board could direct a new election to be held as soon as June.

U.S. Won't Intervene In Arizona Death Case

FLORENCE, Ariz., April 21 (AP) — Honduran officials today demanded that Arizona halt the execution of a citizen who they say was denied his rights under an international treaty.

But Federal officials declined to intervene, and the Honduran citizen, Jose Roberto Villafuerte, was set to die by injection early Wednesday. Mr. Villafuerte, 45, was sentenced to death in the 1983 killing of Amelia Schoville, who suffocated after she was left bound and gagged in Mr. Villafuerte's trailer in Phoenix.

Arizona's Board of Executive Clemency today voted 4 to 1 against recommending commutation of Mr. Villafuerte's death sentence.

The State Department acknowledged that Arizona officials violated the Vienna Convention treaty by failing to notify Honduras of Mr. Villafuerte's arrest. The department urged the clemency panel to consider the violation, but stopped short of asking officials to halt the execution.

Last week, the State Department asked Virginia to halt the execution of a Paraguayan man for similar reasons. The man was executed.

The New York Times

WEDNESDAY, APRIL 22, 1998

School subsidy proposal defeated in Senate vote

The Senate, voting largely along party lines, defeated on Tuesday a Democratic plan backed by President Clinton to subsidize school construction with \$11 billion in federal funds. The defeat, 56-42, was expected.

Republicans are supporting a bill to let tax-free savings accounts be used for school expenses.

Clinton has said he would veto the savings bill, already passed by the House, because it would mostly benefit families sending their children to private school.

"The right way to fix schools is to fix them, not walk away from them," Clinton said.

"They believe it's OK for Congress to invest money in highly specific, local transportation projects, but not to give even the most general kind of support for our education infrastructure," he added.

He was referring to a \$217 billion transportation bill passed by the Republican-dominated House.

NEW GREEN CARDS: Seeking to slow down counterfeiters, the Immigration and Naturalization Service unveiled on Tuesday a high-tech green card for legal immigrants who reside permanently in the USA. The INS spent \$38 million developing the plastic card, which replaces a laminated paper version. It uses sophisticated technologies such as digital photos and optical memory stripes with encrypted information that can be read by scanner. INS officials say they hope the new design, which features micro-dot portraits of all the nation's presidents, will make it easier to detect fakes.

PRESIDENT TO ADDRESS GRADS: President Clinton will address the 1998 graduating classes of the U.S. Naval Academy on May 22, Massachusetts Institute of Technology on June 5 and Oregon's Portland State University on June 13, the White House announced Tuesday. Vice President Gore has commencement speeches scheduled at South Carolina State University on May 9 and New York University on May 14.

JUICE SAFETY: The Food and Drug Administration proposed on Tuesday that warning labels be placed on containers of juice that is not treated to kill disease-causing microbes. The FDA hopes to implement the labeling plan by the fall apple harvest when more untreated juice is sold. The FDA estimates there are from 16,000 to 48,000 cases of juice-related illnesses each year in the United States. In 1996, the dangerous E. coli O157 bacteria contaminated one brand of bottled apple juice, killing one child and making at least 66 people sick. People also have become infected with salmonella in orange juice.

CAMPAIGN FINANCE: Supporters of overhauling the campaign finance system gained ground Tuesday in their drive to force the measure to the House floor over the objections of the GOP leadership. Three Republican lawmakers and two Democrats added their names to a petition demanding the issue be debated on the floor, and other lawmakers have said they are ready to join them. GOP Reps. Amo Houghton of New York, Tom Davis of Virginia and Zach Wamp of Tennessee, as well as Democrats Bennie Thompson of Mississippi and recently elected Rep. Barbara Lee of California brought the number of signatures to 200. That's 18 shy of the total needed to force the hand of the leadership. House Republican leaders discussed the petition drive at a closed-door meeting but came to no conclusion about how to proceed, according to one official who spoke on condition of anonymity.

Written by Ken Washington with staff and wire reports

USDA lets meat plants fix nonfood violations

By Curt Anderson
ASSOCIATED PRESS

After 13 plant shutdowns since January, the Agriculture Department is giving meat and poultry plants new chances to fix violations themselves as long as the problem doesn't involve tainted food.

Since implementation of a new inspection system three months ago in the 312 largest plants, industry officials have frequently complained that the Agriculture Department took action without adequately notifying companies involved.

In response, USDA's Food Safety and Inspection Service put together a formal procedure that allows plants three business days to address problems that could subject them to a costly shutdown.

"We think it addresses their concerns. It's fair. It's a balanced approach," Thomas Billy, administrator of the inspection service, said yesterday.

None of the 13 shutdowns under the new inspection method — known as the Hazard Analysis and

Critical Control Point system, or HACCP — stemmed from confirmed contamination by hazardous microbes such as E. coli, Mr. Billy said. Most involved failure to adequately document preventive measures such as proper temperature control or problems with sanitation.

The shutdowns ranged from a few hours to three days, Mr. Billy said. He added that 92 percent of the big plants — which slaughter 75 percent of the nation's livestock — have complied with the new system.

"By and large, it has worked very well," he said.

The idea behind HACCP is to identify the points in the manufacturing process where contamination is likely to occur and do something to prevent it. The job of a federal inspector is changing into one geared more toward monitoring whether the company is doing that properly.

When an inspector cites a particular problem over and over, it is eventually considered a system failure and can result in a plant

shutdown through withdrawal of all government inspectors. But 11 meat and poultry organizations protested that the rule was vague and being enforced unevenly.

"The proposal provides neither notice and an opportunity for hearing prior to withdrawal of inspection, nor for any time limit on the agency's decision once inspection is withdrawn," said the National Meat Association in a letter.

The new USDA plan, Mr. Billy said, "provides an opportunity for a plant to make changes or adjustments that would avoid us taking more formal action."

When contaminated product has left the plant, however, production could still be immediately halted.

In addition, the department has created a new formal appeals process for a company to protest an agency decision and is increasing training for supervisors so they can better understand and analyze a plant's HACCP system. There will also be more scientific advice and technical support for inspectors.

Many of the changes announced yesterday are aimed at next January, when an additional 3,000 medium-size processing plants must have HACCP systems in place and officials hope to have any early bugs worked out.

"This is sort of a work in progress," Mr. Billy said.

Fruit Juice

QUESTIONS AND ANSWERS ON PROPOSED JUICE REGULATIONS

April 20, 1997

Q: What is the Administration announcing with regard to food safety?

A: The Clinton Administration will announce two proposed regulations by the Food and Drug Administration (FDA) to improve the safety of fruit and vegetable juices.

The first would require that all fruit and vegetable juice processors implement a Hazard Analysis and Critical Control Point (HACCP) system for their products to protect the public from health hazards. This regulation will ensure that processors take extra steps to reduce the numbers of microorganisms that may be in their products to an amount roughly equivalent to that achieved by pasteurization. The proposed HACCP regulation does not prescribe what these steps must be, allowing the processor the flexibility to choose a technique that fits into this process and is effective. Retailers of packaged juice, as well as processors who sell less than 40,000 gallons of fresh juice per year, would be exempt from this requirement.

The second proposed rule would require any packaged untreated juice to be labeled with a warning statement advising consumers of the potential risks of juice that has not been processed to eliminate dangerous bacteria. This requirement will apply to retail and other processors who package untreated juice for consumption off-site -- such as grocery stores that squeeze and bottle juice for home use. But retail sellers of juice for consumption on-site -- such as restaurants and juice bars -- will be exempt from this labeling requirement.

As a result of this requirement, consumers would see labels on juice products that give them important information about the product. If the juice has not undergone pasteurization or a comparable treatment, a consumer would see a warning statement such as: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

Q: When will these regulations become effective? How will these regulations affect this juice season?

A: It is proposed that the HACCP regulation become effective one year after publication of the final rule with a two or three year phase-in period for small and very small businesses. FDA is asking for comment on the appropriate length of the phase-in period. Under the proposal, these processors would be required to label until they implement HACCP. Implementing a HACCP program requires planning, training of personnel, and possibly the purchase of new equipment by producers. For these reasons, it is not feasible to make the rules effective for the next cider season.

FDA plans to have the labeling regulation in place by September of this year, in time for

the 1998 cider season. Because of the short effective date, FDA has proposed allowing flexibility in how the warning statement appears. While FDA intends to require that the warning statement appear on the label of the product itself, we are proposing a phase-in period until January 1, 2000 (January 1, 2001 for small businesses) during which the statement can appear on placards, signs, or other point-of-purchase materials so long as such labeling is prominent enough to effectively inform consumers.

Q: How much juice is expected to be pasteurized as a result of the proposed rules?

A: Currently, about 98 percent of all juice sold in the United States is pasteurized. However, it is expected that up to 40 million additional gallons of juice will be pasteurized as the result of these proposed rules. As a result, FDA expects that these proposals will reduce the number of illnesses significantly.

Q: Are juices safe?

A: Juice products, in general, are safe and nutritious foods. Currently, about 98 percent of juice sold in the United States is pasteurized. However, the growing record of consumer illness in recent years demonstrates that a problem exists with respect to unpasteurized products. During the past several years, outbreaks of foodborne illness have been associated with the consumption of juice and beverages containing juice that have not been pasteurized or otherwise treated to destroy pathogens.

Unfortunately, we do not know the actual number of juice-related illnesses because these types of illness are underreported. Individuals may not experience all of the symptoms or have severe enough symptoms to seek medical attention. Additionally, medical personnel may simply treat the symptoms without determining the underlying cause.

Q: Should children drink unpasteurized juice?

A: FDA advises consumers that, due to the increased risk of illness from pathogens, unpasteurized juice not be given to children, the elderly, or anyone who has a significantly weakened immune system.

Q: Would the proposed rules apply to imported juice products?

A: The rules would apply to all juice products sold in interstate commerce, including all imported juice products.

Q: How will FDA enforce these rules?

A: As proposed, FDA will have authority to conduct official reviews of all of the records associated with maintaining a HACCP system to ensure that producers are in compliance with the proposed requirements. If a producer is out of compliance or does not have a HACCP program, any product offered for sale by that establishment would be considered

adulterated and subject to seizure. If a firm fails to meet the labeling requirement, FDA can take any of several kinds of enforcement actions, including seizing the food.

Q: What are the costs of the rules?

A: The benefits and costs of the rules will be specified in a joint regulatory impact analysis to be published in the Federal Register. However, the benefits overall greatly exceed the costs of the rules.

Q: Will there be an additional cost to consumers?

A: Whether an individual producer chooses to pass on any additional costs is up to that producer. But we do not expect many consumers to see significant increases in price in fruit juices as a result of this regulation.

Q: What is HACCP?

A: HACCP stands for Hazard Analysis and Critical Control Point system. It is a systematic approach to the identification, assessment, and prevention of all types of risk -- biological, chemical, and physical -- that may occur in a food production process or practice. When implementing a HACCP system, a food producer develops a plan that anticipates and identifies the points in the production process where a failure to control the process would likely result in contamination of the food. HACCP is regarded as the state-of-the-art means to ensure the safety and integrity of the food supply.

Q: How do the juice regulations fit into the President's Food Safety Initiative?

A: When President Clinton announced the Food Safety Initiative, HACCP rules for seafood and for meat and poultry were highlighted as an important part of improving the food safety system in this country. Expanding HACCP to other appropriate foods, particularly juice, was one of the key goals. In fact, the President noted when introducing the Food Safety Initiative in his radio address on January 25, 1997, that no parent should have to be concerned about the juice they pour for their child at breakfast.

FDA to Propose Juice Safety Regulations

Aim Is to Prevent Contamination; Some Products Would Get Warning Labels

By JOHN F. HARRIS
Washington Post Staff Writer

The Clinton administration this week will announce new regulations designed to improve the safety of juices, in particular fresh-squeezed varieties such as the bacteria-tainted apple juice that caused one death and widespread illness in western states in 1996.

While many consumers buy expensive fresh-squeezed juices on the belief that they are more healthful, food safety experts say the opposite often is true if these juices have not been pasteurized or undergone other procedures to kill disease-causing organisms.

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Contaminated juices are not a widespread public health problem. The vast majority of juices—some 98 percent—on the market are already pasteurized, regardless of whether they are fresh or made from concentrate, according to government and industry officials.

Even so, in recent years considerable attention has focused on the 2 percent that is not treated. In perhaps the most notori-

ous episode, a 16-month-old Colorado girl died and some 70 other people in Washington and other states became severely ill in 1996 by drinking Odwalla brand apple juice.

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Administration officials said those juice bottlers who already pasteurize their products would most likely have little trouble meeting the new standards, although they must also demonstrate that they are monitoring for pesticide residue and glass shards in their products.

The new regulations also would allow for exceptions. Stores that sell juice for drinking on the premises, such as juice bars, would not be affected. Grocery stores and other retail outlets that press their own juice for sale on the premises but not for broader distribution would not have to pasteurize, but their products would have to carry the warning labels.

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searching for issues that resonated with average voters and were looking for ways to counter conservative claims that the federal government should be scaled back sharply.

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The assumption until not long ago, she said, was that juices were acidic enough to prevent bacteria from growing. The Odwalla case and others like it in recent years have shown this is not the case.

Without the new rules, she said, "we'll reach the point where we'll have to keep children and elderly from drinking cider."

MONDAY, APRIL 20, 1998
The Washington Post

First Juice

Reverse Oppos. on o' tobacco

Bill Builds to Hazardous Levels

By CECI CONNOLLY
Washington Post Staff Writer

When lawmakers return to Washington this week, they will discover that opposition to comprehensive anti-smoking legislation has been steadily building—in some of the most unusual corners.

Constituencies as diverse as button-down Chamber of Commerce types and fast food junkies are preparing an aggressive campaign to revise or kill a national tobacco policy crafted by Sen. John McCain (R-Ariz.). In most cases, objections have little to do with the dangers of smoking. But the alliances signal a new, and potentially deadly, phase for this year's biggest legislative initiative.

"The tobacco industry has orchestrated this thing very well," said Bill Novelli, a veteran of the anti-smoking movement. "Retailers pop up one day, alcohol the next. This is a real grass-roots tussle that will not be lost on members of Congress in an election year."

The National Restaurant Association, part of the network forming against the tobacco legislation, represents 170,000 eateries. "The best thing about representing restaurants is they're in every district," said the association's Lee Culpepper, emphasizing his members' close contact with lawmakers.

Though not formally organized, the loose coalition includes some of Big Tobacco's most reliable partners (bar owners, tobacco growers and convenience store operators) as well as those who seemingly have little in

common with the cigarette business (insurance companies, drug stores, anti-tax advocates and the American Civil Liberties Union).

Some object on philosophical grounds, others fear for their own livelihood and many simply worry Congress is heading down a slippery slope: today, cigarettes; tomorrow, who knows? After all, one Yale University psychologist waging his own crusade against fatty foods asserted: "To me, there is no difference between Ronald McDonald and Joe Camel."

If McCain and the White House cannot revive momentum for the \$516 billion plan to discourage smoking, it could die of a thousand tiny cuts.

"If it was solely the American Civil Liberties Union or the pension funds over tobacco stocks, it wouldn't be such a problem for the legislation," said Ross Baker, a congressional scholar at Rutgers University. "But the more diverse the opposition becomes, and particularly the more unconventional the alliances, it usually spells trouble."

After a brief period of detente, cigarette executives resumed hostilities earlier this month. RJR Nabisco chief executive Steven Goldstone declared that he and other major cigarette company leaders were abandoning talks with Congress because the price tag on the proposed legislation would bankrupt the industry. They vowed to use their vast resources to battle on Capitol Hill and in courtrooms across America. As lobbyist J. Philip Carlton put it: "We're fighting for our life."

Industry spokesman Scott Williams said their battle plan to defeat the legislation is secret, but he acknowledged cigarette makers are busily wooing industries with a financial stake in the legislation. As one executive familiar with industry thinking put it: "We've got to go back and see if our traditional allies are ready to jump on."

Already, tobacco's representatives have contacted the American Wholesale Marketers Association, friendly Wall Street analysts and several farm

groups. A national advertising campaign has begun, and there is talk of a series of town hall-style meetings hosted by cigarette executives to try to convince the public that Congress is more interested in raising taxes and paying for new spending programs than in curbing youth smoking.

Combine anti-taxers, tobacco growers and many of America's 50 million smokers and you have "a potent combination," said a worried Novelli, the anti-smoking advocate.

Cigarette companies—and other industries affected by the tobacco legislation—contribute huge sums to elected officials. Common Cause reported Friday that alcohol and restaurant interests gave more than \$26 million to the Democratic and Republican parties from 1987 to 1997. Philip Morris gave \$100,000 to the National Republican Congressional Committee, the largest contribution the committee took in during the first three months of 1998, according to the Federal Election Commission.

Because tobacco is politically radioactive, few of the groups wish to

be tied to cigarette makers. "We don't want to be viewed in the same light they're viewed," said Marc Katz, a lobbyist for the National Association of Convenience Stores.

Yet their interests often merge. A group of convenience store operators met with McCain in Phoenix Friday to urge him to modify parts of the bill that permit the Food and Drug Administration to decide what types of stores can sell tobacco products. A victory on that front would be great news for cigarette makers because convenience stores are one of the largest markets for cigarette sales.

And their messages frequently track talking points developed by tobacco's high-priced public relations experts.

"Tobacco is just the first step," said John R. Block, a former agriculture secretary and president of Food Distributors International. "If you can attack tobacco with these horrendous taxes, why not do the same to liquor? How about beer? Then maybe go after beef because it's kinda fatty."

Warehouse owners, worried that

TODAY IN CONGRESS

SENATE

Meets at 11 a.m.
Committees: none.

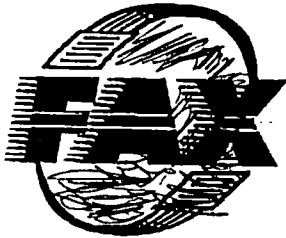
HOUSE

Not in session.
Committees: none.

—LEGI-SLATE Inc.

The Washington Post

MONDAY, APRIL 20, 1998



U.S. FOOD AND DRUG ADMINISTRATION
OFFICE OF THE COMMISSIONER
OFFICE OF POLICY
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857
Room: 14-101 Mail Code: HF-11
Office Phone: 301-827-3360
Fax Number: 301-594-6777

lockhart
244-
6447

Supers: 1888-897-
5078

Levit
Oliver
205-4102

Date:

To: TOM FREEDMAN

Fax Number: 202-458-7431

From: Bill Hubbard

Pages (w/o cover): 2

Comments: Here is a brief
summary of the
juric issue with OIRA.

Schultz
Home: 202-363-1236
Hubbard
703 241-8423
301-708 3332

deaths
hazard

→ Don Markle →
→ JPL.

Laurie M.
301-914
0457

Labeling

Levit
6244

301 827 8276

244 3397
301-320-3093

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 Mary L. Smith
04/14/98 02:45:24 PM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP
cc:
Subject: Re: Distance Learning for Rural Areas

Here is some ideas for rural -- I will try to set up a meeting with Kalil. Let me know.

----- Forwarded by Mary L. Smith/OPD/EOP on 04/14/98 02:46 PM -----

 **Thomas A. Kalil**
02/20/98 05:40:55 PM 

Record Type: Record

To: Mary L. Smith/OPD/EOP
cc: Thomas L. Freedman/OPD/EOP
bcc:
Subject: Re: Distance Learning for Rural Areas 

Mary L. Smith

 Mary L. Smith
02/20/98 10:47:01 AM

Record Type: Record

To: Thomas A. Kalil/OPD/EOP
cc: Thomas L. Freedman/OPD/EOP
Subject: Distance Learning for Rural Areas

Tom and I have been asked to come up with a list of rural/farmer issues. Is there anything going on with distance learning, particularly in rural communities? Do you know of any other rural initiatives that you think we should be pushing? Thanks, Mary

#1. Learning Anytime, Anywhere -- not just rural -- but will be especially helpful to rural

#2. Distance Learning and Telemedicine program
<http://www.usda.gov/rus/dlt/dlml.htm>

#3. FCC program to provide discounts to rural health care facilities

<http://www.fcc.gov/healthnet/>

Not yet up and running

#4. New idea -- digital library for Rural America. Imagine that farmers and other rural Americans could easily search:

all of the research funded at our land grant colleges

"lessons learned" from rural development programs in housing, tourism

etc., etc.

I did a write-up for this for the Rural Fund for America, and got some language on telecom in the solicitation, but didn't do a whole lot of follow-up with USDA.

Let me know if you are interested.

EXAMPLES OF COVERAGE UNDER THE JUICE RULES

	Labeling	HACCP
Large processor of fresh juice	yes -- only until HACCP implemented	yes
small processors (including roadside stands) selling more than 40,000 gallons of fresh juice per year	yes -- only until HACCP implemented	yes
small processors (including roadside stands) selling less than 40,000 gallons of fresh juice per year such as very small cider mills	yes	no
retailers selling fresh, packaged juice produced on site (e.g. juice sold by the pint or gallon) such as a grocery store	yes	no
retailer selling fresh juice for consumption on-site (e.g. by the glass) including restaurants, juice bars, and children's lemonade stands	no	no

*Fruit***QUESTIONS AND ANSWERS ON PROPOSED JUICE REGULATIONS****April 20, 1997**

Q: What is the Administration announcing with regard to food safety?

A: The Clinton Administration will announce two proposed regulations by the Food and Drug Administration (FDA) to improve the safety of fruit and vegetable juices. The first would require that all fruit and vegetable juice processors implement a Hazard Analysis and Critical Control Point (HACCP) system for their products to protect the public from health hazards. Retailers of packaged juice, including processors who sell less than 40,000 gallons of fresh juice per year, would be exempt from HACCP but would instead be required to place warning labels on their products. The second proposed rule would require packaged untreated juice to be labeled with a warning statement advising consumers of the potential risks of juice that has not been processed to eliminate dangerous bacteria. Retail sellers of juice for consumption on-site -- such as restaurants, juice bars, and children's lemonade stands -- will be exempt from this labeling requirement. However, retailer processors who package untreated juice for consumption off-site -- such as grocery stores that squeeze and bottle juice for home use -- will be required to label.

Q: What effect will these regulations have?

A: Processors of fresh, unpasteurized juices would be required to take extra steps to reduce the numbers of microorganisms that may be in their products to an amount roughly equivalent to that achieved by pasteurization. The proposed HACCP regulation does not prescribe what these steps must be, allowing the processor the flexibility to choose a technique that fits into his process and is effective. Prior to having a HACCP program in place, processors who do not pasteurize or use a comparable process would be required to include a warning statement on their label. Retailers of packaged fresh juice, including those who sell less than 40,000 gallons of fresh juice per year, would be exempt from HACCP but would instead be required to place warning labels on their products. Retail processors selling juice that is consumed on-site would be exempt from this labeling requirement. Examples of these types of processors include restaurants, juice bars, and children's lemonade stands.

Consumers would expect to see labels on juice products that give them important information about the product. If the juice has not undergone pasteurization or a comparable treatment, a consumer would see a warning statement such as: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

Q: When will these regulations become effective? How will these regulations affect this juice season?

A: It is proposed that the HACCP regulation become effective one year after publication of the final rule with a two or three year phase-in period for small and very small businesses. FDA is asking for comment on the appropriate length of the phase-in period. Under the proposal, these processors would be required to label until they implement HACCP. Implementing a HACCP program requires planning, training of personnel, and possibly the purchase of new equipment by producers. For these reasons, it is not feasible to make the rules effective for the next cider season.

FDA plans to have the labeling regulation in place by September of this year, in time for the 1998 cider season. Because of the short effective date, FDA has proposed allowing flexibility in how the warning statement appears. While FDA intends to require that the warning statement appear on the label of the product itself, we are proposing a phase-in period until January 1, 2000 (January 1, 2001 for small businesses) during which the statement can appear on placards, signs, or other point-of-purchase materials so long as such labeling is prominent enough to effectively inform consumers.

Q: How much juice is expected to be pasteurized as a result of the proposed rules?

A: Currently, about 98 percent of all juice sold in the United States is pasteurized. However, it is expected that up to 40 million additional gallons of juice will be pasteurized as the result of these proposed rules.

Q: What is HACCP?

A: HACCP stands for Hazard Analysis and Critical Control Point system. It is a systematic approach to the identification, assessment, and prevention of all types of risk -- biological, chemical, and physical -- that may occur in a food production process or practice. When implementing a HACCP system, a food producer develops a plan that anticipates and identifies the points in the production process where a failure to control the process would likely result in contamination of the food. HACCP is regarded as the state-of-the-art means to ensure the safety and integrity of the food supply.

Q: Has HACCP been successfully implemented for other foods?

A: Yes, HACCP is currently being implemented in the seafood, meat and poultry production industries. Also FDA's low-acid canned food regulations, which have been in place since the 1970s, are HACCP-based regulations.

Q: Are juices safe?

A: Juice products, in general, are safe and nutritious foods. Currently, about 98 percent of juice sold in the United States is pasteurized. However, the growing record of consumer illness in recent years demonstrates that a problem exists that must be dealt with, particularly in unpasteurized products. FDA's proposals are developed to reduce the

potential for foodborne illness and assure that consumers can continue to rely on safe juice products. Unfortunately, we do not know the actual number of juice-related illnesses because these types of illness are underreported. Individuals may not experience all of the symptoms or have severe enough symptoms to seek medical attention. Additionally, medical personnel may simply treat the symptoms without determining the underlying cause. FDA expects that these proposals, when implemented, will reduce the number of illnesses significantly.

Q: What are the problems with juices that are being addressed in the proposed regulations?

A: The proposed regulations will cover a wide range of hazards that may result in foodborne illness, including microbial, chemical, and physical contamination. During the past several years, outbreaks of foodborne illness have been associated with the consumption of juice and beverages containing juice that have not been pasteurized or otherwise treated to destroy pathogens. In the Fall of 1996, an outbreak of *E. coli* O157:H7 from fresh apple juice resulted in 66 illnesses and the death of one child in the western United States and Canada. Other pathogens have also been associated with outbreaks. These include *Salmonella* and *Cryptosporidium* in apple cider, *Bacillus* in orange juice, *Salmonella* in unpasteurized orange juice and in orange drink, and *Vibrio cholerae* in coconut milk.

Illnesses have also been caused by other substances present in juices. Examples include tin leached from the can lining, use of poisonous parts of plants to make the juice, the undeclared presence of food ingredients such as sulfites and FD&C Yellow No. 5, residues from improper sanitation procedures, and the presence of glass, or other hazardous materials. Other types of chemical and physical hazards have the potential to cause illness, such as patulin, a toxin that can occur in juice when excessive levels of moldy apples are used in processing, and toxic elements (e.g., lead). The HACCP proposal will cover these types of hazards, as well as microbial contamination.

Q: Have the problems with juice increased in recent years?

A: Yes, the incidence of illness associated with consumption of fresh juice products has increased in recent years. Some of the microorganisms involved are newly emerging strains such as *E. coli* O157:H7 which has adapted to acidic conditions in foods such as juices and *Cryptosporidium*.

Q: How risky is juice compared to other foods?

A: All foods have the potential to be contaminated with a microbial, chemical, or physical hazard that can cause illness or injury, so, it is impossible to make this comparison. Food producers and manufacturers are aware of this and take steps to minimize the opportunity for contamination to occur. Juices, particularly those not treated to destroy pathogens, provide a potentially favorable environment for supporting the growth of pathogens. However, juices treated to destroy pathogens are generally safe and nutritious.

Q: Should children drink unpasteurized juice?

A: FDA advises consumers that, due to the increased risk of illness from pathogens, unpasteurized juice not be given to children, the elderly, or anyone who has a significantly weakened immune system.

Q: How much juice is consumed in the United States?

A: Americans consume approximately 2.3 billion gallons of juice every year. Juice consumption at both ends of the age spectrum is high. Children under 6 years of age drink 16% of the juice consumed and this amount accounts for 50% of their fruit intake. Adults over 59 consume 20% of the juice. Orange juice is by far the most-consumed juice at 1.4 billion gallons annually. Other popular juices with American consumers are apple juice (166 million gallons), grapefruit juice (166 million), pineapple juice (91 million), tomato and other vegetable juices (78 million), and grape juice (75 million).

Q: How many juice processors are there?

A: There are approximately 3,000 juice processors in the U.S.

Q: Are all juices covered by the regulations?

A: The labeling proposal affects only those packaged juices that have not been pasteurized or otherwise treated to eliminate pathogens. In other words, only packaged, untreated juices will have to bear a warning statement. Juices processed, sold, and consumed in restaurants and similar retail establishments do not require this labeling. All retailers, however, including restaurants as well as producers who sell less than 40,000 gallons of fresh juice per year, would be exempt from HACCP.

Q: Would the proposed rules apply to imported juice products?

A: The rules would apply to all juice products sold in interstate commerce, including all imported juice products.

Q: How do the juice regulations fit into the President's Food Safety Initiative?

A: When President Clinton announced the Food Safety Initiative, HACCP rules for seafood and for meat and poultry were highlighted as an important part of improving the food safety system in this country. Expanding HACCP to other appropriate foods, particularly juice, was one of the key goals. In fact, the President noted when introducing the Food Safety Initiative in his radio address on January 25, 1997, that no parent should have to be concerned about the juice they pour for their child at breakfast.

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than \$40 million to the FY '98 budget. With that money we started putting in place new science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget seeks an even more substantial increase in resources, \$101 million, to improve food safety. The President's initiative includes: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and further expanding our early warning system and strengthening state surveillance activities for foodborne illnesses.

Q: How will FDA enforce these rules?

A: As proposed, FDA will have authority to conduct official reviews of all of the records associated with maintaining a HACCP system to ensure that producers are in compliance with the proposed requirements. If a producer is out of compliance or does not have a HACCP program, any product offered for sale by that establishment would be considered adulterated and subject to seizure. If a firm fails to meet the labeling requirement, FDA can take any of several kinds of enforcement actions, including seizing the food.

Q: What are the costs of the rules?

A: The benefits and costs of the rules will be specified in a joint regulatory impact analysis to be published in the Federal Register. However, the benefits overall greatly exceed the costs of the rules.

Q: Will there be an additional cost to consumers?

A: Whether an individual producer chooses to pass on any additional costs is up to that producer. However, an additional cost for juice is a small price to pay for the large margin of safety gained.

Final

DRAFT
**CLINTON ADMINISTRATION ANNOUNCES NEW MEASURES
TO INCREASE SAFETY OF FRESH JUICES**
April 20, 1998

The Administration will announce the publication of two new proposed rules to increase the safety of fruit and vegetable juices. The new regulations would affect all juices, but have special provisions to help control illnesses that may come from fresh, unpasteurized juices, and require labels to alert those most at risk of food-borne illness such as children and the elderly. The rules would require most juice processors to implement a Hazard Analysis and Critical Control Point (HACCP) program, and require processors of fresh juices to greatly reduce the number of microbes in their products. HACCP is a state of the art, science-based method in which food producers develop plans that identify and control potentially dangerous points in the production process. The proposed rules also would require that all packaged fresh juice be labeled with a warning advising consumers of the potential risks of juice that has not been processed to eliminate harmful bacteria. The Food and Drug Administration estimates that there are up to 48,000 cases of juice-related illness each year.

The application of the HACCP rules to juices is part of the President's Food Safety Initiative. HACCP rules have already been promulgated by the Administration for meat, poultry, and seafood.

Reducing Hazards and Increasing Safety for Fresh Juices. The new HACCP rule would require processors that sell fresh, unpasteurized fruit and vegetable juices to take extra steps to reduce the number of microbes in their products to an amount roughly equivalent to that achieved by pasteurization. Juice processors would be free to implement any method that achieves a targeted 100,000-fold reduction in the numbers of microbes in the finished product including pasteurization, washing, scrubbing, antimicrobial solutions, alternative technologies, or a combination of these techniques. The HACCP proposed rules also would require processors to develop standard operating procedures under HACCP for monitoring plant and equipment sanitation and to keep records to ensure product safety. Retailers of packaged juice such as grocery stores and very small processors would not be subject to the HACCP requirement, but would be required to have warning labels on their products. Locations where juice is consumed on premises, such as a child's lemonade stand, juice bar, or restaurant would not be affected by the HACCP or labeling requirements.

Providing Warning Label for Consumers. The Administration will announce additional proposed rules that would require warning labels on juice products that have not been processed to reduce microbial risk. These labels would state that the product has not been treated to eliminate microbes; that the product may contain pathogens known to cause serious illness; and that the risk is greatest for children, the elderly, and people with weakened immune systems. These labels would be required for all packages of untreated, fresh juices but not for juice sold for on-site consumption such as in restaurants. The Administration expects to finalize this rule in time for the apple harvest this September.

Clinton Administration Accomplishments In Improving Food Safety

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

*February, 1998. Administration announces its proposed food safety budget, which requests an approximate \$101 million increase for food safety initiatives.

*May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply --"Food Safety from Farm to Table" -- detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

*January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop foodborne disease outbreaks quickly and to improve prevention systems further.

*August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

*August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

*July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

*December, 1995. Administration issues new rules to ensure seafood safety, utilizing HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

Shirley
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Jeff R.

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Clark Capen

Max Fine

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property

AR 18

Apr. 20

X

5 people

Lori Miller

418
556 5175

Regress

Support/oppose settlement: 45-32 (indy's support least)

Immunity is future suits is a killer, especially among women (38-50 prefer no settlement)

Dems and Indys trust Clinton on tobacco, and D's are more trusted than Rs

Skinny bill is supported 74-23, and 68-27 when people know R's sponsored it, 65-29 with argumentation that it doesn't go far enough

comp bill aint worth waiting for

ban ads at kids

we should use 2nd hand smoke

I predict the House splits extreme rt and left. They get skinny bill

Senate gets to floor and moves left.

It goes to conference. Cut deal.

The more centralized the target, the more left the bill becomes. Hence conference is our friend, even though politics aren't true.

TO: MARY ELLSW

From: BRUCE

222 - 7684

DRAFT

DRAFT
**CLINTON ADMINISTRATION ANNOUNCES NEW MEASURES
TO INCREASE SAFETY OF FRESH JUICES**
April 20, 1998

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Top News

Report: Odwalla in Plea Deal Talks

Sports

SEATTLE (AP) -- A company that produced unpasteurized apple juice linked to an E. coli outbreak in 1996 is negotiating a plea agreement in which it would admit to federal food-safety violations, a newspaper reported today.

Lotteries

International

National

The bacterial outbreak linked to Odwalla apple juice killed a Colorado girl and made nearly 70 other people ill in Washington, other states and British Columbia.

Washington

Business

Odwalla Inc. is likely to agree to a deal in which it would plead guilty to about a dozen misdemeanor charges related to food-safety deficiencies at its Dinuba, Calif., production plant, the Seattle Post-Intelligencer reported, citing unidentified sources.

Wall Street

Entertainment

No company officials would be charged, but the company would pay a \$1.5 million criminal fine, the sources said.

Health/Science

Regional

The only larger fine in an adulterated-food case in the United States was \$2 million paid by Beech-Nut Nutrition Corp. in 1987 for selling phony apple juice intended for babies, the paper said.

Unless negotiations break down, the Odwalla plea agreement is expected to be filed in federal court in California in the next few weeks, the sources said.

A federal grand jury in Fresno, Calif., has been investigating whether Odwalla, based in Half Moon Bay, Calif., ignored safety standards at the time of the outbreak.

Assistant U.S. Attorney Joseph Johns, who has headed the investigation, said he could neither confirm nor deny that a plea deal had been reached. Odwalla spokesman Chris Gallagher also declined to comment.

Company executives have acknowledged their safety systems didn't keep out the bacteria and said they didn't realize E. coli could live in something as acidic as apple juice. The company has since begun pasteurizing its apple juice.

Odwalla also faces at least two lawsuits filed by the families of two children who fell ill.

(PROFILE (CO:Odwalla Inc; TS:ODWA; IG:BVG;) (CAT:Business;) (CAT:Consumer;))

□AP-NY-04-15-98 1006EDT

4TH STORY of Level 2 printed in FULL format.

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The San Francisco Examiner

April 3, 1997, Thursday; Second Edition

SECTION: NEWS; Pg. A-7

LENGTH: 547 words

HEADLINE: Public outcry over FDA food policing ;
Critics say tainted berries just latest snafu; ask Clinton to form new agency

SOURCE: OF THE EXAMINER STAFF

BYLINE: GEORGE RAINE

BODY:

The Food and Drug Administration is under attack by critics who say the possible exposure of thousands of U.S. schoolchildren to tainted Mexican -grown strawberries is the latest in "a bumper crop of food safety problems."

The critics, assembled by the Center for Science in the Public Interest, which monitors health matters, Wednesday assailed the FDA for alleged gaps in performance of its duties. They called on President Clinton to form an independent federal food agency "to assure American consumers that these food hazards will be fully addressed."

At a news conference in Washington, Laurie Girard of Saratoga, whose 3-year-old daughter, Anna McGregor, ~~last year became~~ ill allegedly by drinking unpasteurized apple juice produced by Half Moon Bay-based Odwalla Inc., said she favored a centralized agency to ensure protection from tainted products.

"I'm scandalized that the United States government is letting the food industry use children as guinea pig testers for how safe their products are," she said.

The Center for Science in the Public Interest said that in 1996 it had counted more than 1,000 illnesses from a parasite on raspberries; several hundred illnesses, and one death, of 16-month-old Anna Gimmetstad, of Evans, Colo., from E. coli bacterial infection allegedly associated with Odwalla apple juice; and several dozen deaths and hundreds of illnesses from shellfish.

"Many of these are examples of new and emerging food safety problems," said Bill Bryant of the center. "However, the agency in charge of these hazards, the Food and Drug Administration, is poorly funded and inadequately staffed to address these serious public health problems. This puts American consumers at risk."

Technically, the Department of Agriculture is responsible for the school lunch program, which received tainted strawberries. The FDA has jurisdiction.

In Odwalla's case, the company began immediately to work with the FDA and the Centers for Disease Control and Prevention to discover the E. coli source, and it recalled its apple juice and other juice products. The company then voluntarily began to "flash pasteurize" its apple juice, a rapid -heating

The San Francisco Examiner, April 3, 1997

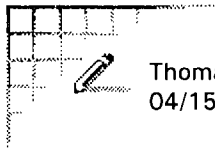
process used in milk production that kills bacteria, when it was returned to market.

Then, in December, Odwalla and FDA and other health officials met to discuss proposed regulations.

"This administration has put a very strong emphasis on food safety and protecting American families. We have done that by forging closer relationships among the agencies that have responsibility for food safety," said James O'Hara, the FDA's associate commissioner for public affairs.

LANGUAGE: English

LOAD-DATE: April 04, 1997



Thomas L. Freedman
04/15/98 10:52:28 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP
cc: Mary L. Smith/OPD/EOP
Subject: FYI: Odwalla story moved at 10 am on AP

Report: Odwalla in Plea Deal Talks

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EXAMPLES OF COVERAGE UNDER THE JUICE RULES

	Labeling	HACCP
Large processor of fresh juice	yes -- only until HACCP implemented	yes
small processors (including roadside stands) selling more than 40,000 gallons of fresh juice per year	yes -- only until HACCP implemented	yes
small processors (including roadside stands) selling less than 40,000 gallons of fresh juice per year such as very small cider mills	yes	no
retailers selling fresh, packaged juice produced on site (e.g. juice sold by the pint or gallon) such as a grocery store	yes	no
retailer selling fresh juice for consumption on-site (e.g. by the glass) including restaurants, juice bars, and children's lemonade stands	no	no

B. N. Schultze
 Larose Branch
 408-267-9300

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The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

*February, 1998. Administration announces its proposed food safety budget, which requests an approximate \$101 million increase for food safety initiatives.

*May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply --"Food Safety from Farm to Table" -- detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

*January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop foodborne disease outbreaks quickly and to improve prevention systems further.

*August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

*August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

*July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

*December, 1995. Administration issues new rules to ensure seafood safety, utilizing HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

4130
418**QUESTIONS AND ANSWERS ON PROPOSED JUICE REGULATIONS****April 20, 1997****Q: What is the President announcing today?**

A: The President is announcing two proposed regulations by the Food and Drug Administration (FDA) to improve the safety of fruit and vegetable juices. The first would require that all fruit and vegetable juice processors implement a Hazard Analysis and Critical Control Point (HACCP) system for their products to protect the public from health hazards. Retailers of packaged juice, including those who sell less than 40,000 gallons of fresh juice per year, would be exempt from HACCP but would instead be required to place warning labels on their products. The second proposed rule would require packaged untreated juice to be labeled with a warning statement advising consumers of the potential risks of juice that has not been processed to eliminate dangerous bacteria. Retail sellers of juice for consumption on-site -- such as restaurants, juice bars, and children's lemonade stands -- will be exempt from this labeling requirement. However, retailer processors who package untreated juice for consumption off-site -- such as grocery stores that squeeze and bottle juice for home use -- will be required to label.

Q: What effect will these regulations have?

A: Processors of fresh, unpasteurized juices would be required to take extra steps to reduce the numbers of microorganisms that may be in their products to an amount roughly equivalent to that achieved by pasteurization. The proposed HACCP regulation does not prescribe what these steps must be, allowing the processor the flexibility to choose a technique that fits into his process and is effective. Prior to having a HACCP program in place, processors who do not pasteurize or use a comparable process would be required to include a warning statement on their label. Retailers of packaged juice, including those who sell less than 40,000 gallons of fresh juice per year, would be exempt from HACCP but would instead be required to place warning labels on their products. Retail processors selling juice that is consumed on-site would be exempt from this labeling requirement. Examples of these types of processors include restaurants, juice bars, and children's lemonade stands.

Consumers would expect to see labels on juice products that give them important information about the product. If the juice has not undergone pasteurization or a comparable treatment, a consumer would see a warning statement such as: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

Q: When will these regulations become effective? How will these regulations affect this juice season?

- A:** It is proposed that the HACCP regulation become effective one year after publication of the final rule with a two or three year phase-in period for small and very small businesses. FDA is asking for comment on the appropriate length of the phase-in period. Under the proposal, these businesses would be required to label until they implement HACCP. Implementing a HACCP program requires planning, training of personnel, and possibly the purchase of new equipment by producers. For these reasons, it is not feasible to make the rules effective for the next cider season.

FDA plans to have the labeling regulation in place by September of this year, in time for the 1998 cider season. Because of the short effective date, FDA has proposed allowing flexibility in how the warning statement appears. While FDA intends to require that the warning statement appear on the label of the product itself, we are proposing a phase-in period until January 1, 2000 (January 1, 2001 for small businesses) during which the statement can appear on placards, signs, or other point-of-purchase materials so long as such labeling is prominent enough to effectively inform consumers.

Q: What is HACCP?

- A:** HACCP stands for Hazard Analysis and Critical Control Point system. It is a systematic approach to the identification, assessment, and prevention of all types of risk -- biological, chemical, and physical -- that may occur in a food production process or practice. When implementing a HACCP system, a food producer develops a plan that anticipates and identifies the points in the production process where a failure to control the process would likely result in contamination of the food. HACCP is regarded as the state-of-the-art means to ensure the safety and integrity of the food supply.

Q: Has HACCP been successfully implemented for other foods?

- A:** Yes, HACCP is currently being implemented in the seafood, meat and poultry production industries. Also FDA's low-acid canned food regulations, which have been in place since the 1970s, are HACCP-based regulations.

Q: Are juices safe?

- A:** Juice products, in general, are safe and nutritious foods. Currently, about 98 percent of juice sold in the United States is pasteurized. However, the growing record of consumer illness in recent years demonstrates that a problem exists that must be dealt with, particularly in unpasteurized products. FDA's proposals are developed to reduce the potential for foodborne illness and assure that consumers can continue to rely on safe juice products. Unfortunately, we do not know the actual number of juice-related illnesses because these types of illness are underreported. Individuals may not experience all of the symptoms or have severe enough symptoms to seek medical attention. Additionally, medical personnel may simply treat the symptoms without determining the underlying cause. Factoring in this underreporting, it is possible to estimate that the

combined effect of these 2 proposals will prevent between 16,000 and 48,000 illnesses annually.

Q: What are the problems with juices that are being addressed in the proposed regulations?

A: The proposed regulations will cover a wide range of hazards that may result in foodborne illness, including microbial, chemical, and physical contamination. During the past several years, outbreaks of foodborne illness have been associated with the consumption of juice and beverages containing juice that have not been pasteurized or otherwise treated to destroy pathogens. In the Fall of 1996, an outbreak of *E. coli* O157:H7 from fresh apple juice resulted in 66 illnesses and the death of one child in the western United States and Canada. Other pathogens have also been associated with outbreaks. These include *Salmonella* and *Cryptosporidium* in apple cider, *Bacillus* in orange juice, *Salmonella* in unpasteurized orange juice and in orange drink, and *Vibrio cholerae* in coconut milk.

Illnesses have also been caused by other substances present in juices. Examples include tin leached from the can lining, use of poisonous parts of plants to make the juice, the undeclared presence of food ingredients such as sulfites and FD&C Yellow No. 5, residues from improper sanitation procedures, and the presence of glass, or other hazardous materials. Other types of chemical and physical hazards have the potential to cause illness, such as patulin, a toxin that can occur in juice when excessive levels of moldy apples are used in processing, and toxic elements (e.g., lead). The HACCP proposal will cover these types of hazards, as well as microbial contamination.

Q: Have the problems with juice increased in recent years?

A: Yes, the incidence of illness associated with consumption of fresh juice products has increased in recent years. Some of the microorganisms involved are newly emerging strains such as *E. coli* O157:H7 which has adapted to acidic conditions in foods such as juices and *Cryptosporidium*.

Q: How risky is juice compared to other foods?

A: All foods have the potential to be contaminated with a microbial, chemical, or physical hazard that can cause illness or injury, so, it is impossible to make this comparison. Food producers and manufacturers are aware of this and take steps to minimize the opportunity for contamination to occur. Juices, particularly those not treated to destroy pathogens, provide a potentially favorable environment for supporting the growth of pathogens. However, juices treated to destroy pathogens are generally safe and nutritious.

Q: Should children drink unpasteurized juice?

A: FDA advises consumers that, due to the increased risk of illness from pathogens,

unpasteurized juice not be given to children, the elderly, or anyone who has a significantly weakened immune system.

Q: How much juice is consumed in the United States?

A: Americans consume approximately 2.3 billion gallons of juice every year. Juice consumption at both ends of the age spectrum is high. Children under 6 years of age drink 16% of the juice consumed and this amount accounts for 50% of their fruit intake. Adults over 59 consume 20% of the juice. Orange juice is by far the most-consumed juice at 1.4 billion gallons annually. Other popular juices with American consumers are apple juice (166 million gallons), grapefruit juice (166 million), pineapple juice (91 million), tomato and other vegetable juices (78 million), and grape juice (75 million).

Q: How many juice processors are there?

A: There are approximately 3,000 juice processors in the U.S.

Q: Are all juices covered by the regulations?

A: The labeling proposal affects only those juices that have not been pasteurized or otherwise treated to eliminate pathogens. In other words, only fresh, untreated juices will have to bear a warning statement. Juices processed, sold, and consumed in restaurants and similar retail establishments do not require this labeling. These juices are less than 3% of all juice on the market. Retailers of packaged juice, including those who sell less than 40,000 gallons of fresh juice per year, would be exempt from HACCP but would instead be required to place warning labels on their products.

Q: Would the proposed rules apply to imported juice products?

A: The rules would apply to all juice products sold in interstate commerce, including all imported juice products.

Q: How do the juice regulations fit into the President's Food Safety Initiative?

A: When President Clinton announced the Food Safety Initiative, HACCP rules for seafood and for meat and poultry were highlighted as an important part of improving the food safety system in this country. Expanding HACCP to other appropriate foods, particularly juice, was one of the key goals. In fact, the President noted when introducing the Food Safety Initiative in his radio address on January 25, 1997, that no parent should have to be concerned about the juice they pour for their child at breakfast.

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than \$40 million to the FY '98 budget. With that money we started putting in place new

science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget seeks an even more substantial increase in resources, \$101 million, to improve food safety. The President's initiative includes: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and further expanding our early warning system and strengthening state surveillance activities for foodborne illnesses.

Q: How will FDA enforce these rules?

A: As proposed, FDA will have authority to conduct official reviews of all of the records associated with maintaining a HACCP system to ensure that producers are in compliance with the proposed requirements. If a producer is out of compliance or does not have a HACCP program, any product offered for sale by that establishment would be considered adulterated and subject to seizure. If a firm fails to meet the labeling requirement, FDA can take any of several kinds of enforcement actions, including seizing the food.

Q: What are the costs of the rules?

A: The costs of both rules is estimated at \$30 million in the first year and \$20 million annually in subsequent years. These total costs are far exceeded by the total annual benefits of between \$350 and \$483 million.

Q: Will there be an additional cost to consumers?

A: Whether an individual producer chooses to pass on any additional costs is up to that producer. However, an additional cost for juice is a small price to pay for the large margin of safety gained.

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	Labeling	HACCP
Large processor of fresh juice	only until HACCP implemented	yes
roadside stand selling more than 40,000 gallons per year	only until HACCP implemented	yes
roadside stand selling less than 40,000 gallons per year	yes	no
retailer who packages untreated juice for consumption off-site, including grocery stores	yes	no
retailer who sell for consumption on-site including restaurants, juice bars, and children's lemonade stands	no	no

More info

FROM PROPOSAL PREAMBLE

**FOOD AND DRUG ADMINISTRATION
OFFICE OF PUBLIC AFFAIRS - HFI-21
WASHINGTON, D.C.**

**PHONE: (202) 205-4144
FAX: (202) 205-5169 OR
(202) 205-4050**

TO: Tom Freedman
(Receiver)

Arthur Whitmore
**FROM: FDA PRESS OFFICE
HFI-21 -- FB8
ROOM 3807**

(Agency/Company)

456-7431

(Fax Number)

MESSAGE:

Juice docs - per request by Sharon Mayle

TOTAL PAGES: _____

DATE: _____

also faxed to Jordan TAMMEN,

Shady
COPY

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 26 1998

Food and Drug Administration

21 CFR Part 120

RIN 0910-AA43

[Docket No. 97N-0511]

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to adopt regulations to ensure the safe and sanitary processing of fruit and vegetable juices and juice products. The proposed regulation, if adopted, will mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of these foods. HACCP is a preventive system of hazard control. FDA is proposing these regulations because there have been a number of outbreaks of illness, including some directly affecting children, associated with juice products and because a system of preventive control measures is the most effective and efficient way to ensure that these products will be safe. Elsewhere in this issue of the **Federal Register**, FDA is publishing a warning label proposal for juice and a preliminary regulatory impact analysis for both proposals.

DATES: Submit written comments by *(insert date 75 days after date of publication in the Federal Register)*. For information on the proposed compliance dates for small businesses and very small businesses see the **SUPPLEMENTARY INFORMATION** section of this document.

Submit written comments on the information collection and recordkeeping requirements by *(insert date 30 days after the date of publication in the Federal Register)*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Submit written comments regarding information collection and recordkeeping requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503. Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4681.

SUPPLEMENTARY INFORMATION:

The agency proposes to make any final rule based upon this proposal effective 1 year after its date of publication in the **Federal Register**. However, by its terms, the final rule will not be binding on small businesses as defined in proposed § 120.1(b)(1) until 2 years after the date of publication of a final rule in the **Federal Register**; and for very small businesses as defined in proposed § 120.1(b)(2), the final rule will not be binding until 3 years after the date of its publication in the **Federal Register**.

I. Concerns With Juice

A. Microbial Outbreaks

The Seattle-King County Department of Public Health and the Washington State Department of Health reported on October 30, 1996, an outbreak of *Escherichia coli* O157:H7 infections epidemiologically associated with drinking a particular brand of unpasteurized apple juice, or juice mixtures containing unpasteurized apple juice, purchased from a coffee shop chain, grocery stores, and other locations (Ref. 1). A case was defined as hemolytic uremic syndrome (HUS) or a stool culture yielding *E. coli* O157:H7 in a person who became ill after September 30, 1996, after drinking the particular brand of juice within 10 days before illness onset. There were at least 66 cases of illness, with 14 cases of HUS and the death of one child, associated with this outbreak

(Ref. 2). Cases occurred in British Columbia, California, Colorado, and Washington. *E. coli* O157:H7 isolates cultured from a previously unopened container of the particular brand of apple juice had a deoxyribonucleic acid (DNA) "fingerprint" pattern (restriction fragment length polymorphism) indistinguishable from case-related isolates (Ref. 1).

Various juices have been documented as vehicles for causing outbreaks from microorganisms. A 1967 outbreak from contaminated water added to orange juice concentrate affected approximately 5,200 persons and was caused by an unidentified virus and possibly other contaminants (Refs. 3 and 4). About 300 people became ill from *Salmonella typhimurium* in cider made from apples, including some that had been picked up from the ground in an orchard fertilized with manure, in a 1974 outbreak in New Jersey (Ref. 5). A 1991 outbreak of *Vibrio cholerae* was associated with coconut milk contaminated during manufacturing in Thailand (Ref. 6). There have been two *Cryptosporidium* outbreaks related to drinking apple cider, the first in Maine in 1993 and the other in New York State in 1996. In the first case, the apples used for cider came from trees near a cow pasture (Ref. 7), and in the second case, water used for rinsing came from a well that tested positive for coliforms (Ref. 8). In 1995 there was an outbreak in Florida that was caused by *Salmonella hartford* in unpasteurized orange juice (Ref. 9).

E. coli O157:H7 has been recognized relatively recently as a human pathogen and has been a source of a number of outbreaks related to juice. Thirteen and possibly 14 children had bloody diarrhea and developed HUS in Toronto, Canada, between September 15 and 25, 1980. The children's illnesses were associated with drinking fresh apple juice. The children's stools were examined for enteropathogenic *E. coli*, *Campylobacter*, *Salmonella*, *Shigella*, and *Yersinia*. None of these organisms were found. *E. coli* O157:H7 is the suspected causative organism. Conclusive testing for that organism was not done because *E. coli* O157:H7 was not recognized as a human pathogen before 1982 (Ref. 10).

A 1991 *E. coli* O157:H7 outbreak in southeast Massachusetts conclusively showed that fresh-pressed unpasteurized apple juice can transmit *E. coli* O157:H7 bacteria. In this outbreak, 23 individuals had diarrhea, 16 had bloody diarrhea, and 4 developed HUS (Ref. 11).

In Connecticut, a 1996 outbreak of *E. coli* O157:H7 illness was associated with drinking a particular brand of apple cider. There were 14 cases of illness (including 7 hospitalized), with 3 cases of HUS associated with the outbreak (Ref. 8).

There was a small outbreak of *E. coli* O157:H7 illness in Washington State in 1996 that was related to apple cider made at a church event. This outbreak occurred during the same time as the unpasteurized apple juice outbreak described in previous paragraphs. The apples were washed in a chlorine solution, but it was not reported how much chlorine was used. Six people became ill, but no estimate was given on how many people may have drunk the apple cider (Ref. 12).

FDA's recall data also provide evidence of microbial hazards in juice. There were 85 cases of illness in 1994 resulting in a recall of orange juice that had fermented and contained *Bacillus cereus* and yeast (Ref. 13).

State investigations provide additional evidence of microbial hazards in juice. A 1989 outbreak in New York was caused by the presence in orange juice of *Salmonella typhi* that originated from an infected worker and resulted in 69 illnesses with 21 individuals hospitalized (Ref. 14). The State of Washington reported that in 1993 one individual was hospitalized from home-made carrot juice found to contain *Clostridium botulinum* (Ref. 15). A 1993 Ohio outbreak caused by yeast or some other unknown toxicant in orange juice resulted in 23 illnesses (Ref. 16). A home-made watermelon drink contaminated with *Salmonella* spp. caused illness in 18 individuals in a 1993 Florida outbreak (Ref. 17). The State of Colorado reported two outbreaks of gastrointestinal illness from fresh squeezed orange juice at a mountain resort (Ref. 18). There were food handlers that were ill in both Colorado instances, and a virus was suspected as the causative agent.

Clearly, the evidence shows that fruit and vegetable juices have been the vehicle for outbreaks of foodborne illnesses. Although fruit juice is acidic, and thus would generally be considered to

inhibit the growth of most microorganisms, most juice-related outbreaks have been associated with fruit juices.

B. Illnesses From Nonheat-treatable Hazards

Illnesses that have been caused by hazards that can not be reduced to acceptable levels by heat treatments have also been associated with juice. Tin in canned tomato juice caused illness in 113 individuals in 1969 (Ref. 19). Soil nitrate had resulted in a high nitrate content in the tomatoes, and this high nitrate content accelerated detinning in the cans. In 1984, 11 persons became ill from consuming elderberry juice containing poisonous parts of the plant (Ref. 20). A 1990 guanabana juice outbreak was caused by the presence of toxic guanabana seed material and caused illness in nine individuals (Ref. 21). A 1997 outbreak was caused by tin in pineapple juice (Ref. 22).

In 1992 an 18-month-old child with a blood lead level of 36 micrograms per deciliter ($\mu\text{g}/\text{dL}$) was found in a routine county health department blood lead monitoring program. Investigation of this incident by the county health department revealed that the only significant source of lead exposure for this child was lead in imported fruit juice packed in 12-ounce, lead-soldered cans (Ref. 23). Analysis by the State health department of multiple flavors of the fruit juices in lead-soldered cans available to the child found lead levels ranging from 160 to 810 parts per billion (ppb). An exposure assessment performed by the county health department estimated that the child consumed about three cans of these fruit juices per day and estimated that the child's daily lead intake from these fruit juices was approximately 600 $\mu\text{g}/\text{day}$ (Ref. 23). As a result of this incident, FDA announced an emergency action level of 80 ppb for lead in fruit beverages (such as juices, nectars, and drinks) packed in lead-soldered cans (58 FR 17233, April 1, 1993). The agency subsequently banned the use of lead-soldered cans (60 FR 33106, June 27, 1995).

Recalls also provide evidence of nonheat-treatable hazards in juice. In 1988 a fruit punch drink was recalled because of the presence of tin caused by the acidity of the drink reacting with the tin coating of the cans (Ref. 24). The product had been packaged in the wrong container.

There were 10 recalls between 1990 and 1995 for fruit juice or beverages containing fruit juice because of the presence of food ingredients that were inadvertently added to the product, not declared on the label, or not suitable for the food. Food ingredients involved with these recalls were natamycin (Ref. 25), sulfites (Ref. 26), FD&C yellow No. 5 (Refs. 27 through 33), and salt (Ref. 34).

Five recalls between 1991 and 1997 were caused by improper sanitation procedures or faulty equipment. In 1991 sodium hydroxide from a clean-in-place system contaminated the caps of a citrus punch drink (Ref. 35). In 1992 three persons became ill, with 1 hospitalized, from a sodium hydroxide sanitizing agent that got into fruit drink product containers during cleaning (Ref. 36). In 1993 cracks in a heat exchanger allowed an orange flavored soft drink containing pear juice to come in contact with copper pipe fittings and, thus, to become contaminated with copper (Ref. 37). In 1994 milk was found in orange juice from filler lines that were not cleaned between milk and juice production (Ref. 38). In 1997 the presence of an alkaline cleaning solution in a berry juice caused gastrointestinal distress in several persons (Ref. 39).

Companies have recalled fruit drinks because pieces of glass or plastic were found in their products. The presence of glass in products is typically caused by the use of glass bottles, which can chip or shatter during the production process (Refs. 40 through 42). The plastic was present from the company's practice of draping plastic bags over the side of the bottle loading bin (Ref. 43).

One company recalled apple-prune juice and prune juice in 1996 because of unacceptable levels of lead (Refs. 46 and 47). The cause was contaminated imported prune juice.

In response to the establishment of maximum levels for patulin in apple juice by several foreign governments, FDA initiated a sampling survey to determine the levels commonly found in domestic and imported apple juice. Patulin may be present in juice made from moldy apples. In March 1997 the agency found inordinately high levels of patulin in apple juice from a processor in Washington State (Ref. 48). The level of patulin found in the product was sufficient to pose

a health hazard, especially considering the fact that apple juice is commonly used by infants and young children (Ref. 49). All affected product that had left the plant had been used in the manufacture of fermented apple cider. Patulin could not be detected in fermented product, and it was assumed that the patulin was destroyed through the fermentation process.

Therefore, as the foregoing discussion reveals, the evidence demonstrates that juice and juice beverages are susceptible to chemical and physical hazards as well as microbiological hazards.

C. Underreporting

There is wide agreement that the laboratory-confirmed cases from outbreaks and recalls understate the actual number of juice-related cases, but no consensus exists on the size of the understatement. Individuals may not manifest all symptoms or have severe enough symptoms to necessitate medical attention. Medical personnel may simply treat an individual's symptoms without determining the underlying cause. The laboratory-confirmed cases only represent those cases where individuals sought medical attention, and where medical personnel performed the necessary testing and reported the case to a government agency.

The total number of juice-related illnesses can be estimated by multiplying the average number of laboratory-confirmed cases by factors that account for under-reporting. The factors are based on the relationships between annual outbreak cases and published estimates of the number of foodborne illnesses. For example, it is estimated that the average 16 annual laboratory-confirmed cases of *Salmonella* represents 4,900 to 7,600 actual cases (Ref. 50). For *E. coli* O157:H7, an average 22 laboratory-confirmed cases per year may actually represent 2,200 to 4,300 total juice-related cases (Ref. 50). Therefore, the actual number of illnesses from the outbreaks described in sections I.A and I.B of this document is much greater than the confirmed number of illnesses. Although the actual number is unknown, it may be estimated by scientific means.

Summary of June

Argentina \$163 -97 18%

Chile

Brazil \$146

16%

Mexico \$167

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Chile \$164

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**U.S. FOOD AND DRUG ADMINISTRATION
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To: Tom Freedman/Mary Smith

Fax Number: (202) 456-7431

From: Sharon Lindan Mayl

Date: April 16, 1998

Pages (w/o cover): 6

Comments:

I am faxing draft Qs and As that should be helpful in putting together remarks.

QUESTIONS AND ANSWERS ON PROPOSED JUICE REGULATIONS

What is the President announcing today?

The President is announcing two proposed regulations by the Food and Drug Administration to improve the safety of fruit and vegetable juices.

What do the proposals do?

There are two proposed regulations. The first would require that all juice processors, except retail processors, of both fruit and vegetable juices implement a HACCP system for their products to protect the public from health hazards. The second is intended as an interim measure of protection before the HACCP system is in place and would require packaged fresh juice to be labeled with a warning statement advising consumers of the potential risks of juice that has not been processed to eliminate dangerous bacteria.

What effect will these regulations have?

Processors, except retail processors, of fresh, unpasteurized juices would be required to take extra steps to reduce the numbers of microorganisms that may be in their products to an amount roughly equivalent to that achieved by pasteurization. The proposed HACCP regulation does not prescribe what these steps must be, allowing the processor the flexibility to choose a technique that fits into his process and is effective. Prior to having a HACCP program in place, processors who do not pasteurize or use a comparable process would be required to include a warning statement on their label. However, retail processors selling juice that is consumed on-site are exempt from this labeling requirement. Examples of these types of processors include restaurants, juice bars, and a child with the lemonade stand. The retail processor who packages the untreated juice for consumption off-site, such as a grocery store that squeezes and bottles orange juice for home use, is required to do labeling.

Consumers can expect to see labels on juice products that give them important information about the product. If the juice has not undergone pasteurization or a comparable treatment, a consumer may see a warning statement such as: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems".

What is HACCP?

HACCP stands for Hazard Analysis and Critical Control Point system. It is a systematic approach to the identification, assessment, and prevention of all types of risk -- biological, chemical, and physical -- that may occur in a food production process or practice. When implementing a HACCP system, a food producer develops a plan that anticipates and identifies the points in the production process where a failure to control the process would likely result in contamination of the food. HACCP is regarded as the state-of-the-art means to ensure the safety and integrity of the food supply.

Has HACCP been successfully implemented for other foods?

Yes, HACCP is currently being implemented in the seafood, meat and poultry production industries. Also FDA's low-acid canned food regulations, which have been in place since the 1970s, are HACCP-based regulations.

Why isn't HACCP applied to every food product?

HACCP allows processors to assess their procedures on an ongoing basis and make changes to deal with any problems they find. As FDA gains experience from pilot programs and seafood HACCP implementation, it will consider expanding the scope of mandatory HACCP requirements to include other foods as the need arises.

Are juices safe?

Juice products, in general, are safe and nutritious foods. However, the growing record of consumer illness in recent years demonstrates that a problem exists that must be dealt with, particularly in unpasteurized products. FDA's proposals are developed to reduce the potential for foodborne illness and assure that consumers can continue to rely on safe juice products.

How many people have been injured by contaminated juice?

Since 1982, approximately 500 confirmed cases of foodborne illness traceable to contaminated juice have been reported, including the 1996 outbreak caused by fresh apple juice that resulted in 66 cases of illness and the death of one child. Unfortunately, we do not know the actual number of juice-related illnesses because these types of illness are underreported. Individuals may not experience all of the symptoms or have severe enough symptoms to seek medical attention. Additionally, medical personnel may simply treat the symptoms without determining the underlying cause. Factoring in this underreporting, it is possible to estimate that the combined effect of these 2 proposals will prevent between 16,000 and 48,000 illnesses annually and 4 or 5 deaths. **Note: The number of illnesses may change as a result of recalculations to accomodate the changes in the draft regs.**

What are the problems with juices that are being addressed in the proposed regulations?

The proposed regulations will cover a wide range of hazards that may result in foodborne illness, including microbial, chemical, and physical contamination. During the past several years, outbreaks of foodborne illness have been associated with the consumption of juice and beverages containing juice that have not been pasteurized or otherwise treated to destroy pathogens. In the Fall of 1996, an outbreak of *E. coli* O157:H7 from fresh apple juice resulted in 66 illnesses and the death of one child in the western United States and Canada. Other pathogens have also been associated with outbreaks. These include *Salmonella* and *Cryptosporidium* in apple cider, *Bacillus* in orange juice, *Salmonella* in unpasteurized orange juice and in orange drink, and *Vibrio cholerae* in coconut milk.

Illnesses have also been caused by other substances present in juices. Examples include tin leached from the can lining, use of poisonous parts of plants to make the juice, the undeclared presence of food ingredients such as sulfites and FD&C Yellow No. 5, residues from improper

sanitation procedures, and the presence of glass, or other hazardous materials. Other types of chemical and physical hazards have the potential to cause illness, such as patulin, a toxin that can occur in juice when excessive levels of moldy apples are used in processing, and toxic elements (e.g., lead). The HACCP proposal will cover these types of hazards, as well as microbial contamination.

Have the problems with juice increased in recent years?

Yes, the incidence of illness associated with consumption of fresh juice products has increased in recent years. Some of the microorganisms involved are newly emerging strains such as *E. coli* O157:H7 which has adapted to acidic conditions in foods such as juices and *Cryptosporidium*.

Which juices pose the highest risk?

Apple juice/cider that has not been treated to destroy pathogens, such as *E. coli* O157:H7, is associated with the greatest incidence and severity of reported illnesses.

How risky is juice compared to other foods?

All foods have the potential to be contaminated with a microbial, chemical, or physical hazard that can cause illness or injury, so, it is impossible to make this comparison. Food producers and manufacturers are aware of this and take steps to minimize the opportunity for contamination to occur. Juices, particularly those not treated to destroy pathogens, provide a potentially favorable environment for supporting the growth of pathogens. However, juices treated to destroy pathogens are generally safe and nutritious.

Should children drink unpasteurized juice?

FDA advises consumers that, due to the increased risk of illness from pathogens, unpasteurized juice not be given to children, the elderly, or anyone who has a significantly weakened immune system.

How much juice is consumed in the United States? By whom?

Americans consume approximately 2.3 billion gallons of juice every year. Juice consumption at both ends of the age spectrum is high. Children under 6 years of age drink 16% of the juice consumed and this amount accounts for 50% of their fruit intake. Adults over 59 consume 20% of the juice.

What juices are consumed most?

Orange juice is by far the most-consumed juice at 1.4 billion gallons annually. Other popular juices with American consumers are apple juice (166 million gallons), grapefruit juice (166 million), pineapple juice (91 million), tomato and other vegetable juices (78 million), and grape juice (75 million).

How many juice processors are there?

There are approximately 3,000 juice processors in the U.S.

Why not require pasteurization for juice rather than mandating HACCP systems?

Pasteurization cannot replace a HACCP system. First of all, pasteurization may be too prescriptive a standard for attaining the level of juice safety that FDA is proposing. There are currently other technologies that may be used to achieve the same level of safety for certain juices. Furthermore, FDA wishes to provide the flexibility for processors to use new technologies as they are developed. Second, while pasteurization may eliminate or reduce the microbial hazard, a HACCP system will control the chemical (such as toxic elements and naturally-occurring toxins) and physical (glass and metal) hazards.

Is juice pasteurization the same as milk pasteurization?

Essentially, yes. Both milk and juice pasteurization involve time and temperature-dependent heat treatments to destroy pathogens. The exact combination of time and temperature used will vary with the type of juice and whether the juice is to be stored in the refrigerator or on the pantry shelf.

Are all juices covered by the regulations?

The labeling proposal affects only those juices that have not been pasteurized or otherwise treated to eliminate pathogens. In other words, only fresh, untreated juices will have to bear a warning statement. Juices processed, sold, and consumed in restaurants and other similar retail establishments do not require this labeling. These juices are less than 3% of all juice on the market.

The HACCP regulation covers all juice processors, except retailers.

What about roadside cider stands?

A roadside stand that presses the juice at the stand does not have to have a HACCP system but it will have to label if it is sold for consumption off-site. If it sells juice pressed elsewhere, the juice processor will have to have the HACCP plan.

What about a child's lemonade stand?

Juice that is produced and consumed on-site at retail will not have to be labeled or be processed under a HACCP system. This exemption would include juice bars and restaurants.

Would the proposed rules apply to imported juice products?

The rules would apply to all juice products sold in interstate commerce, including all imported juice products.

When will these regulations become effective? How will these regulations affect this juice season?

It is proposed that the HACCP regulation become effective one year after publication of the final rule with a two or three year phase-in period for small and very small businesses. FDA is asking

for comment on the appropriate length of the phase-in period and on the need for a longer phase-in period (perhaps 5 years) for those very small business that process 40,000 or fewer gallons of juice annually. FDA is also seeking comment on including, in the definition of "retailer", very small businesses (total production 40,000 or fewer units annually) that process juice on premises for consumption on-site, but also have limited sales off-premise. Implementing a HACCP program requires planning, training of personnel, and possibly the purchase of new equipment by producers. For these reasons, it is not feasible to make the rules effective for the next cider season.

The agency plans to have the labeling regulation in place by September of this year, in time for the 1998 cider season. Because of the short effective date, the agency has proposed allowing flexibility in how the warning statement appears. While the agency intends to require the warning statement appear on the label of the product itself, we are proposing a phase-in period until January 1, 2000 (January 1, 2001 for small businesses) during which the statement can appear on placards, signs, or other point-of-purchase materials so long as such labeling is prominent enough to effectively inform consumers.

How will these regulations affect small businesses?

The proposed HACCP regulation gives small juice processors additional time to comply and asks for comment on the length of the phase-in period (3 or 5 years) for very small processors (e.g., those that process 40,000 or fewer gallons annually).

How much of the past problem would be solved by this regulation?

HACCP controls would greatly reduce the occurrence of microbial, chemical, and physical contamination that has caused problems in the past. The performance standard in the HACCP regulation would likely have eliminated the pathogens that caused most of the problems with juices in the past, including the recent apple juice illnesses and deaths.

How do the juice regulations fit into the President's Food Safety Initiative?

When President Clinton announced the Food Safety Initiative, HACCP rules for seafood and for meat and poultry were highlighted as an important part of improving the food safety system in this country. Expanding HACCP to other appropriate foods, particularly juice, was one of the key goals. In fact, the President noted when introducing the Food Safety Initiative in his radio address on January 25, 1997, that no parent should have to be concerned about the juice they pour for their child at breakfast.

Why has it taken so long for FDA to act when the dangers were so well documented?

The rulemaking process depends on a thorough evaluation of all the available data and options. During this process, FDA published a notice last August explaining the steps the agency intended to take to enhance the safety of juices, including issuing these proposals, and urged processors to voluntarily take preventive steps to prevent microbial contamination and to label unpasteurized juices. In addition, the agency embarked on an education campaign for consumers, distributing information on juice safety to 7,500 state and local extension agents for use in their consumer

education programs and to 80,000 day-care providers and elementary school principals, and providing articles to more than 10,000 newspapers. On the processor side, FDA has also participated in workshops on safe production of juice products targeted to small processors in several regions of the U.S.

How will FDA enforce these rules?

As proposed, FDA will have authority to conduct official reviews of all of the records associated with maintaining a HACCP system to ensure that producers are in compliance with the proposed requirements. If a producer is out of compliance or does not have a HACCP program, any product offered for sale by that establishment would be considered adulterated and subject to seizure. If a firm fails to meet the labeling requirement, FDA can take any of several kinds of enforcement actions, including seizing the food.

What are the costs of the rules?

~~The costs of both rules is estimated at \$50 million in the first year and \$30 million annually in subsequent years. These total costs are far exceeded by the total annual benefits of \$170 million.~~

Note: These numbers are being recalculated based on changes made to the proposed regs.

Will there be an additional cost to consumers?

Whether an individual producer chooses to pass on any additional costs is up to that producer. However, an additional cost for juice is a small price to pay for the large margin of safety gained.

What are the juices that are consumed in greatest quantities in the U.S.?

There are several. Apple, orange, grape, cranberry, grapefruit, and tomato juices are among those consumed in the greatest amounts.

Many consumers enjoy fresh squeezed orange juice purchased at retail outlets — will that have to be pasteurized?

Pasteurization will not be mandatory under the proposed HACCP regulation. When oranges have an intact outer skin, contamination of the interior fruit is unlikely. Processors have various options available for assuring the safety of the juice. For example, the surface of intact oranges may be treated to eliminate any potential contamination. Once the fruit is opened, however, the processor must use appropriate methods to assure the juice does not become contaminated.

**U.S. FOOD AND DRUG ADMINISTRATION
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To: Tom Freedman/Mary Smith

Fax Number: (202) 456-7431

From: Sharon Lindan Mayl

Date: April 16, 1998

Pages (w/o cover): 6

Comments:

I am faxing draft Qs and As that should be helpful in putting together remarks.

QUESTIONS AND ANSWERS ON PROPOSED JUICE REGULATIONS

What is the President announcing today?

The President is announcing two proposed regulations by the Food and Drug Administration to improve the safety of fruit and vegetable juices.

What do the proposals do?

There are two proposed regulations. The first would require that all juice processors, except retail processors, of both fruit and vegetable juices implement a HACCP system for their products to protect the public from health hazards. The second is intended as an interim measure of protection before the HACCP system is in place and would require packaged fresh juice to be labeled with a warning statement advising consumers of the potential risks of juice that has not been processed to eliminate dangerous bacteria.

What effect will these regulations have?

Processors, except retail processors, of fresh, unpasteurized juices would be required to take extra steps to reduce the numbers of microorganisms that may be in their products to an amount roughly equivalent to that achieved by pasteurization. The proposed HACCP regulation does not prescribe what these steps must be, allowing the processor the flexibility to choose a technique that fits into his process and is effective. Prior to having a HACCP program in place, processors who do not pasteurize or use a comparable process would be required to include a warning statement on their label. However, retail processors selling juice that is consumed on-site are exempt from this labeling requirement. Examples of these types of processors include restaurants, juice bars, and a child with the lemonade stand. The retail processor who packages the untreated juice for consumption off-site, such as a grocery store that squeezes and bottles orange juice for home use, is required to do labeling.

Consumers can expect to see labels on juice products that give them important information about the product. If the juice has not undergone pasteurization or a comparable treatment, a consumer may see a warning statement such as: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems".

What is HACCP?

HACCP stands for Hazard Analysis and Critical Control Point system. It is a systematic approach to the identification, assessment, and prevention of all types of risk -- biological, chemical, and physical -- that may occur in a food production process or practice. When implementing a HACCP system, a food producer develops a plan that anticipates and identifies the points in the production process where a failure to control the process would likely result in contamination of the food. HACCP is regarded as the state-of-the-art means to ensure the safety and integrity of the food supply.

Has HACCP been successfully implemented for other foods?

Yes, HACCP is currently being implemented in the seafood, meat and poultry production industries. Also FDA's low-acid canned food regulations, which have been in place since the 1970s, are HACCP-based regulations.

Why isn't HACCP applied to every food product?

HACCP allows processors to assess their procedures on an ongoing basis and make changes to deal with any problems they find. As FDA gains experience from pilot programs and seafood HACCP implementation, it will consider expanding the scope of mandatory HACCP requirements to include other foods as the need arises.

Are juices safe?

Juice products, in general, are safe and nutritious foods. However, the growing record of consumer illness in recent years demonstrates that a problem exists that must be dealt with, particularly in unpasteurized products. FDA's proposals are developed to reduce the potential for foodborne illness and assure that consumers can continue to rely on safe juice products.

How many people have been injured by contaminated juice?

Since 1982, approximately 500 confirmed cases of foodborne illness traceable to contaminated juice have been reported, including the 1996 outbreak caused by fresh apple juice that resulted in 66 cases of illness and the death of one child. Unfortunately, we do not know the actual number of juice-related illnesses because these types of illness are underreported. Individuals may not experience all of the symptoms or have severe enough symptoms to seek medical attention. Additionally, medical personnel may simply treat the symptoms without determining the underlying cause. Factoring in this underreporting, it is possible to estimate that the combined effect of these 2 proposals will prevent between 16,000 and 48,000 illnesses annually and 4 or 5 deaths. **Note: The number of illnesses may change as a result of recalculations to accomodate the changes in the draft regs.**

What are the problems with juices that are being addressed in the proposed regulations?

The proposed regulations will cover a wide range of hazards that may result in foodborne illness, including microbial, chemical, and physical contamination. During the past several years, outbreaks of foodborne illness have been associated with the consumption of juice and beverages containing juice that have not been pasteurized or otherwise treated to destroy pathogens. In the Fall of 1996, an outbreak of *E. coli* O157:H7 from fresh apple juice resulted in 66 illnesses and the death of one child in the western United States and Canada. Other pathogens have also been associated with outbreaks. These include *Salmonella* and *Cryptosporidium* in apple cider, *Bacillus* in orange juice, *Salmonella* in unpasteurized orange juice and in orange drink, and *Vibrio cholerae* in coconut milk.

Illnesses have also been caused by other substances present in juices. Examples include tin leached from the can lining, use of poisonous parts of plants to make the juice, the undeclared presence of food ingredients such as sulfites and FD&C Yellow No. 5, residues from improper

sanitation procedures, and the presence of glass, or other hazardous materials. Other types of chemical and physical hazards have the potential to cause illness, such as patulin, a toxin that can occur in juice when excessive levels of moldy apples are used in processing, and toxic elements (e.g., lead). The HACCP proposal will cover these types of hazards, as well as microbial contamination.

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Average Annual Volume of Production – Apple Cider

Average Volume	% of Cider Producers	% of Total Volume
< 10,000 gals	55	5
< 50,000 gals	88	19
< 100,000 gals	92	22
< 500,000 gals	96	41
< 1 million gals	98	59
> 1 million gals	2	40

Average Annual Value of Cider Sales

Ave. Value of Cider Sale	% of Cider Producers
< \$ 10,000	39
< \$25,000	61
< \$40,000	74
< \$55,000	81
> \$55,000	24

Note: Numbers are based on averages and represent rough estimates.

Dr. John Kvenberg, FDA
August 14, 1997
Page 4

Number of seasonal producers indicating they cease production in:

	Northeast	Southeast	Central	West	National
January	33	3	28	1	65
February	14	2	14	1	31
March	25	3	17	1	46
April	21	1	17		39
May	15	1	13	1	30
June	19	1	9	2	29
August	1		1		2
September			1		1
October	16	3	19	3	41
November	66	10	75	3	154
December	80	19	85	4	188
# Respondents	292	43	279	16	628

Average Annual Volume of Production:

Number of respondents indicating their average annual cider production was:

	Northeast	Southeast	Central	West	National
<5,000 gallons	119	20	127	6	272
5-10,000 gals.	43	8	33	2	86
10-50,000 gals (30,000)	108	10	86	8	212
50-100,000 gals (75,000)	13	1	9	1	24
100-500,000 gals (300,000)	15	2	9	3	29
500,000- 1 million gals (750,000)	6	1	3	1	11
>1 million gals.	5	1	5		11
# Respondents	309	43	272	21	645

Volume

{ 1,360,000
 8,600,000
 6,360,000
 1,800,000
 8,700,000
 8,250,000
 11,000,000
 46,070,000

.42
 .13 55
 .33 88
 .04 92
 .04 96
 .02 98
 .02 100

Dr. John Kvenberg, FDA
August 14, 1997
Page 5

Average Annual Value of Cider Sales:
Number of respondents indicating their average annual value of cider sales was:

	Northeast	Southeast	Central	West	National
> \$9,999	124	14	117	3	258
\$10-24,999	69	17	55	4	145
\$25-39,999	43	6	34	1	84
\$40-54,999	20	1	22	3	46
\$55-69,999	14	1	9	1	25
70-84,999	7		8	2	17
\$85-100,000	9	1	9	1	20
> \$100,000	27	5	24	5	61
# Respondents	313	45	278	20	656

.39
.22
.13
.07
.09
.03
.03
.09

Channels of Sale:
Number of respondents indicating they sell:

	Northeast	Southeast	Central	West	National
Direct to consumer	306	40	274	19	639
In bulk	39	6	28	5	78
To retail/wholesale	154	22	134	14	324
To institutions	48	7	12	4	71
To roadside markets	131	20	68	9	228

+8
6
4
6
17

Number of Respondents Shipping Product Interstate:

Southeast 6
Northeast 37
Central 17
West 4
NATIONAL 64



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Sean is the guy & he
is in town & aware of radio
address

Plan would be to tape this &
put out a Farm Radio network &

Ag Groups.

Send
59674
for

**FOOD AND DRUG ADMINISTRATION
OFFICE OF PUBLIC AFFAIRS - HFI-21
WASHINGTON, D.C.
PHONE: (202) 205-4144
FAX: (202) 205-5169 OR
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TO: Tom Freedman
(Receiver)

Arthur Whitmore
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Juice docs - per request by Sharon Mayle

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Arthur Whitmore (202) 205-4144

FDA PROPOSES MEASURES TO INCREASE SAFETY OF FRESH JUICES

The Food and Drug Administration today proposed regulations to help ensure fruit and vegetable juices -- particularly fresh, unpasteurized juices -- are free from illness-causing microbes and other contaminants. The measures would put special requirements on manufacturers of fresh, unpasteurized juice products because fresh juices are not heat-treated to kill microbes.

The proposals would require all juice processors to implement hazard-control and sanitation procedures at their plants. Processors of fresh, unpasteurized juices would be required to take extra steps to reduce the numbers of microbes in their products to an amount roughly equivalent to that achieved by pasteurization. In addition, special labels would be required on juices that are not pasteurized or otherwise treated to kill microbes.

The special labeling and extra safety steps for fresh juice products would apply only to a relatively small number of processors because most juice sold in the United States -- about 98 percent -- is pasteurized.

"Consumers can rely on the safety of most juice products, particularly juice products which have been pasteurized," said Michael Friedman, M.D., lead deputy commissioner of the Food and Drug Administration. "However, during the past several years, a small but increasing number of consumers have gotten sick from juice products -- usually unpasteurized juices -- because they carried some sort of pathogenic microbe."

"We also want consumers to know that that fresh juices -- which are not pasteurized -- carry a small but real additional risk of carrying bacteria or other pathogenic microorganisms that could cause sickness, and that products that are unpasteurized or otherwise untreated to kill

microbes present a potential risk to young children, the elderly, or anyone who has a ^{weakened} ~~suppressed~~ immune system from cancer treatment, HIV infection or other significant health problem..”

The ^{proposed} rules would require implementation of Hazard Analysis and Critical Control Point (HACCP) programs at all juice processing plants, both foreign and domestic, that sell juice products in the United States. HACCP programs are hazard-control systems designed to prevent contamination of a food product from occurring, or if it does occur, to detect it before the product enters the market. A typical HACCP program imposes specific sanitation procedures and record-keeping requirements on operators of food processing facilities. HACCP programs are already federally required at meat, poultry and seafood processing plants.

As part of their HACCP plans, juice processors would be required to achieve a 100,000-fold reduction in the numbers of microbes in a finished product compared to levels measured at the beginning of the production. This ~~order-of-magnitude~~ is comparable to the microbial reduction achieved by milk pasteurization. Juice processors would be free to employ microbial reduction methods other than pasteurization, including washing, scrubbing, antimicrobial solutions, alternative technologies or a combination of these, as long as they could be shown to achieve the targeted 100,000-fold reduction.

The proposed rule also would require processors to develop standard operating procedures for monitoring plant and equipment sanitation, and to perform monitoring and record keeping necessary to verify and validate HACCP program function and product safety.

A second proposal would require warning labels on juice products that haven't been processed to destroy pathogens. The label would state that the product is not

treated to kill microbes, that the product may contain pathogens known to cause serious illness, and that the risk of serious illness is greatest for children, the elderly and people with weakened immune systems.

Warning labels on untreated juice products would ensure consumers are adequately informed of the risks while HACCP programs are being implemented at processing plants. Warning labels would not be required on juice products that are processed under HACCP programs.

The proposal also would ^{allow manufacturers} require retail outlets such as juice bars that sell untreated juices to post placards on the premises bearing the same warning as that proposed for product labels ^{for a limited time}.

FDA's proposal was developed with input from the public, industry and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), an advisory panel of independent experts who provide guidance to FDA on matters concerning the safety and regulation of foods. In December 1996, FDA convened a two-day public hearing to review the science, technology and manufacturing practices related to the safe production of fresh juices. Following that hearing, the NACMCF concluded that there are safety concerns with juices, especially unpasteurized juices, and recommended that juice processors adopt HACCP programs.

FDA is soliciting comments from the public and industry on its proposals. The ⁵ full proposal ^{is} was published today in the Federal Register. Comments may be submitted for the next 75 days on HACCP issues and the next 30 days on labeling issues to FDA's Dockets Management Branch, HFA-305, Food and Drug Administration, 12410 Parklawn Drive, Room 1-23, Rockville, Md. 20857.

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to allow
for orderly
changing of
labels

Preventing Estimated
16,000 to 48,000
illnesses per year

↓
4 to 5 deaths
per year

No. of Juice Associated Cases per Year (FDA based on Todd)" in Table 11 is calculated in a similar manner.

TABLE 11.—ESTIMATES OF JUICE-ASSOCIATED CASES PER YEAR

Hazard	Severity	Estimate of Under-reporting Correction Factor (FDA based on Bennett)	Estimate of Under-reporting Correction Factor (FDA based on Todd)	Estimate of Actual No. of Juice-Associated Cases per Year (FDA based on Bennett)	Estimate of Actual No. of Juice-Associated Cases per Year (FDA based on Todd)
<i>E. coli</i> O157:H7	Mild	ND	195	ND	1,950
	Moderate	ND	20	ND	130
	Severe-acute	ND	7	ND	30
	Severe-chronic	ND	7	ND	3
	Death	ND	7	ND	4
	Total cases	ND	7	ND	2,100
<i>Salmonella</i> (non typhi)	Mild	307	474	4,340	6,700
	Moderate	307	45	2,010	290
	Severe	246	4	268	4
	Reactive arthritis-short term	307	474	150	230
	Reactive arthritis-long term	307	474	300	460
	Death	246	4	5	1
	Total cases	246	4	6,600	7,000
<i>C. parvum</i>	Mild	100	100	4,300	4,300
	Moderate	10	10	40	40
	Severe	5	5	2	2
	Death	5	5	.04	.04
	Total cases	5	5	4,300	4,300
<i>B. cereus</i>	Mild	96	1,615	2,020	33,980
	Moderate	96	1,615	20	340
	Severe	0	0	0	0
	Death	0	0	0	0
	Total cases	0	0	2,000	34,300

8. Percent of Cases Preventable by Proposal

In general, most pathogens will be eliminated when juice is heat-treated. For example, *Cryptosporidium*, *E. coli* O157:H7, and *Salmonella* should all be completely eliminated from juice by standard methods of flash pasteurization (absent extraordinarily high counts, detrimental human intervention, or equipment failure). However, hazards associated with *B. cereus* will not necessarily be eliminated by heat treatment. This bacterium forms spores which are more difficult to kill by heat. After heat treatment, if the spores survive, they may grow out and produce a toxin which causes illness. Ideally, the best way to reduce illness associated with *B. cereus* is by killing the bacterium in its nonspore state before any toxin has been produced. For most types of heat-treated juice, there is a small probability that the heat treatment will take place when *B. cereus* is in its nonspore state. To the extent that processors adopt controls for these hazards other than flash

Table 4. Heat-Treatable Microbial Hazards

Evidence from outbreaks					
Year	Juice	Hazard	Cases	Cause	Source
1975	Apple cider	<i>Salmonella typhimurium</i>	296	Drop apples; orchard fertilized with cow manure; unpasteurized	CDC 1975
1991	Apple cider	<i>Escherichia coli</i> O157:H7	23; 6 hospitalized; 4 HUS	Drop apples; unpasteurized	Besser et al. 1993
1991	Coconut milk	<i>Vibrio cholerae</i> O1	4 (6 consumed product)	Heavy contamination during manufacturing in Thailand; unpasteurized	Taylor et al. 1993
1993	Apple cider	<i>Cryptosporidium parvum</i>	160	Apples contaminated with calf feces; unpasteurized	Millard et al. 1994
1995	Orange juice	<i>Salmonella</i> Hartford, Gaminara, Rubinslaw	62	Inadequate sanitation and cleaning; unpasteurized	Cook et al. 1996
1996	Apple juice	<i>E. coli</i> O157: H7	66; 14 HUS; 1 death	Unpasteurized	CDC 1996b CDC 1997
1996	Apple cider	<i>E. coli</i> O157: H7	14; 7 hospitalized; 3 HUS	Drop apples; unpasteurized	CDC 1997
1996	Apple cider	<i>E. coli</i> O157: H7	6	Apple cider made at church event	Griffin 1996
1996	Apple cider	<i>C. parvum</i>	31 (20 confirmed)	Unpasteurized; well water used for rinsing contained coliforms	CDC 1997

Evidence from recalls

Year	Juice	Hazard	Cases	Cause	Source
1993	Flavored drinks	<i>C. parvum</i>	Cannot be separated from water-borne cases	From contaminated city water supply	FDA recall data
1996	Orange juice	<i>Bacillus cereus</i> ; yeast	85 cases	Fermented	FDA recall data
1996	Orange Julius drink	<i>Salmonella agona</i>	25		FDA recall data
Evidence from state investigations					
1966	Apple cider	<i>E. coli</i> O157:H7 (suspected; the pathogen was unknown in 1966)	1	Cow manure on clothes of farmer making cider	Personal communication with Marshall Deasy, Pennsylvania State Health Dept., January 15, 1997
1989	Orange juice	<i>Salmonella typhi</i>	69; 21 hospitalized	Infected worker	Personal communication with Mike Cambridge, New York State Health Dept., January 22, 1997
1993	Carrot juice	<i>Clostridium botulinum</i>	1 hospitalized	Home-made	Personal communication with Patty Walker, Washington State Health Dept., January 15, 1997

Year	Juice	Hazard	Cases	Cause	Source
1993	Orange juice	Yeast or unknown toxicant	23; 1 person saw physician	Improper storage time and container	Personal communication with Sharon Karam, Ohio State Health Dept., January 21, 1997
1993	Watermelon drink	<i>Salmonella</i> spp.	18	Home-made	Personal communication with Roberta Hammond, Florida State Health Dept., January 21, 1997
1994	Orange juice	<i>B. cereus</i> ; yeast	21	Juice left at room temperature	Personal communication with Sharon Thompson, Alabama State Health Dept., January 17, 1997

Table 5. Distribution of Severity for Main Microbial Pathogens

Hazard	Distribution of cases by severity (percent)	Characteristics of mild case	Characteristics of moderate case	Characteristics of severe case
<i>Escherichia coli</i> O157:H7	Mild: 50 Moderate: 32 Severe: 18	Nausea, cramping, diarrhea, bloody stools	Nausea, cramping, diarrhea, bloody stools headache, muscle pain, fever, dehydration	Hospitalization; 20 percent develop HUS; 80 percent develop hemorrhagic colitis; case fatality rate = 2-2.5 percent, with HUS and hemorrhagic colitis each accounting for half of fatalities
<i>Salmonella</i> (non typhi)	Mild: 60-70 Moderate: 20-30 Severe: 5-15	Diarrhea, nausea, vomiting, abdominal cramping; lasts 1-2 days	Same as mild, but lasting up to one week	Headache, possible fever, hospitalization; fatal cases about 0.1 percent of total
<i>Cryptosporidium parvum</i>	Mild: 90 Moderate: 9 Severe: 1	Watery diarrhea, lasting one day to several weeks, abdominal cramping	Same as mild, but lasting longer	Hospitalization
<i>Bacillus cereus</i>	Mild: most cases Moderate: rare	Diarrhea, abdominal cramping	Same as mild, with vomiting	

Sources: Council for Agricultural Science and Technology 1994; Mauskopf et al. 1988, Haddix 1997; U.S. Food and Drug Administration 1997.

Aug-15-97 03:14P usapple

Dr. John Kvenberg, FDA
August 14, 1997
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Average Annual Value of Cider Sales:
Number of respondents indicating their average annual value of cider sales was:

	Northeast	Southeast	Central	West	National
> \$9,999	124	14	117	3	258
\$10-24,999	69	17	55	4	145
\$25-39,999	43	6	34	1	84
\$40-54,999	20	1	22	3	46
\$55-69,999	14	1	9	1	25
70-84,999	7		8	2	17
\$85-100,000	9	1	9	1	20
> \$100,000	27	5	24	5	61
# Respondents	313	45	278	20	656

39
22
13
07
09
03
03
09

Channels of Sale:
Number of respondents indicating they sell:

	Northeast	Southeast	Central	West	National
Direct to consumer	306	40	274	19	639
In bulk	39	6	28	5	78
To retail/wholesale	154	22	134	14	324
To institutions	48	7	12	4	71
To roadside markets	131	20	68	9	228

6
4
6
17

Number of Respondents Shipping Product Interstate:

Southeast 6
Northeast 37
Central 17
West 4
NATIONAL 64

DRAFT

**PRESIDENT CLINTON ANNOUNCES NEW MEASURES
TO INCREASE SAFETY OF FRESH JUICES**

April 18, 1998

In his radio address today, President Clinton will announce the publication of a new rule to increase the safety of fruit and vegetable juices. The new regulations effect all juices, but have special provisions to help control illnesses that may come from fresh, unpasteurized juices, and require labels to alert those most at risk of food-borne illness such as children. Specifically, the rules require all juice processors implement a Hazard Analysis and Critical Control Point (HACCP) program, and require processors of fresh juices to greatly reduce the number of microbes in their products. HACCP is a state of the art, science based method in which food producers develop plans that identify and control potentially dangerous points in the production process. As an interim measure, before the HACCP system is in place, the rules require packaged fresh juice to be labeled with a warning statement advising consumers of the potential risks of juice that has not been processed to eliminate bacteria. The Food and Drug Administration estimates that there are up to 48,000 cases of juice-related illness each year.

The application of the HACCP rules to juices is part of the President's Food Safety Initiative. HACCP rules have already been promulgated by the Administration for meat, poultry, and seafood.

Reducing Hazards and Increasing Safety for Fresh Juices. The new rule will require processors that sell fresh, unpasteurized fruit and vegetable juices to take extra steps to reduce the number of microbes in their products to an amount roughly equivalent to that achieved by pasteurization. Juice processors will be free to implement any method that achieves a targeted 100,000-fold reduction in the numbers of microbes in the finished product including pasteurization, washing, scrubbing, antimicrobial solutions, alternative technologies, or a combination of these techniques. The proposed rule also would require processors to develop standard operating procedures under HACCP for monitoring plant and equipment sanitation and to keep records to ensure product safety. These new regulations are aimed at juice manufacturers who distribute their products to consumers and are not directed at the very small processors that sell minimal amounts of juice such as roadside stands. Locations where juice is consumed on premises, such as a roadside stand or restaurant would not be effected.

Providing Warning Label for Consumers. The President will announce additional interim rules for the next three years that require warning labels on juice products that have not been processed to reduce microbial risk. These labels will state that the product has not been treated to eliminate microbes; that the product may contain pathogens known to cause serious illness; and that the risk is greatest for children, the elderly, and people with weakened immune systems. These labels will be required for all manufacturers of fresh juices.

Clinton Administration Accomplishments In Improving Food Safety

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

*February, 1998. Administration announces its proposed food safety budget, which requests an approximate \$101 million increase for food safety initiatives.

*May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply --"Food Safety from Farm to Table" -- detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

*January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop foodborne disease outbreaks quickly and to improve prevention systems further.

*August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

*August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

*July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

*December, 1995. Administration issues new rules to ensure seafood safety, utilizing HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

To: Wendy Taylor

One pager + history

56974

*** TX REPORT ***

TRANSMISSION OK

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To: Wendy Taylor

One pager + history

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5/22 comment ends

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Spencer

Average Annual Volume of Production -- Apple Cider

Average Volume	% of Cider Producers	% of Total Volume
< 10,000 gals	55	5
< 50,000 gals	88	19
< 100,000 gals	92	22
< 500,000 gals	96	41
< 1 million gals	98	59
> 1 million gals	2	40

Average Annual Value of Cider Sales

Ave. Value of Cider Sale	% of Cider Producers
< \$ 10,000	39
< \$25,000	61
< \$40,000	74
< \$55,000	81
> \$55,000	24

Note: Numbers are based on averages and represent rough estimates.

Dr. John Kvenberg, FDA
 August 14, 1997
 Page 4

Number of seasonal producers indicating they cease production in:

	Northeast	Southeast	Central	West	National
January	33	3	28	1	65
February	14	2	14	1	31
March	25	3	17	1	46
April	21	1	17		39
May	15	1	13	1	30
June	19	1	9	2	29
August	1		1		2
September			1		1
October	16	3	19	3	41
November	66	10	75	3	154
December	80	19	85	4	188
# Respondents	292	43	279	16	628

Average Annual Volume of Production:

Number of respondents indicating their average annual cider production was:

	Northeast	Southeast	Central	West	National
<5,000 gallons	119	20	127	6	272
5-10,000 gals.	43	8	33	2	86
10-50,000 gals (30,000)	108	10	86	8	212
50-100,000 gals (75,000)	13	1	9	1	24
100-500,000 gals (300,000)	15	2	9	3	29
500,000- 1 million gals. (750,000)	6	1	3	1	11
>1 million gals.	5	1	5		11
# Respondents	309	43	272	21	645

Volume

1,360,000
 8,600,000
 6,360,000
 1,800,000
 8,700,000
 8,250,000
 11,000,000
 46,070,000

.42
 .13 55
 .33 88
 .04 92
 .04 96
 .02 98
 .02 100

Front
Journals
SW

ary Shalala Backs

Needle-Exchange Program

By a WALL STREET JOURNAL Staff Reporter

WASHINGTON — Health and Human Services Secretary Donna Shalala encouraged local communities to engage in needle-exchange programs to fight AIDS, but she said the federal government wouldn't fund those efforts.

"We have concluded that needle-exchange programs, as part of a comprehensive HIV prevention program, will decrease the transmission of HIV and will not encourage the use of illegal drugs," Ms. Shalala said.

The Clinton administration sought to find a middle ground in the dispute over the controversial programs by supporting the concept of needle-exchange programs but not using federal dollars to pay for them. However, the Christian Coalition took aim at the administration's position. "This is more evidence that sending a consistent moral message to our children really isn't what the Clinton-Gore administration is all about," said Randy Tate, the group's executive director.

FDA to Propose Steps To Improve Safety Of Fresh Fruit Juices

By a WALL STREET JOURNAL Staff Reporter

WASHINGTON — The Food and Drug Administration will propose new regulations this week aimed at improving the safety of fresh fruit juices, particularly those made by small companies and roadside orchards.

About 98% of fruit juices are pasteurized and aren't harmful to consumers. In 1996, some Odwalla brand apple juice contaminated with the bacteria *E. coli* 0157:H7 caused illnesses and one death.

Under the new rules, manufacturers would be required to monitor the production process more closely. In addition, juices that aren't pasteurized will have to carry a label saying they could be harmful to children, the elderly and people with weak immune systems.

But some groups, such as the National Food Processors Association, are calling for even stronger action. Allen Matthys, an association vice president, said the FDA should mandate that all juices be pasteurized or otherwise treated for safety.

"Heat treatment of juice destroys *E. coli* 0157:H7 and other pathogenic microorganisms of public-health concern," he said. "Juice or juice ingredients should receive heat pasteurization or an equivalent process sufficient to render these products free of dangerous microorganisms."

Hemisphere Trade Talks Prod Clinton On 'Fast Track,' but He Won't Act Soon

By ROBERT S. GREENBERGER
And BOB DAVIS

Staff Reporters of THE WALL STREET JOURNAL
WASHINGTON—Despite President Clinton's promise to push for expanded trade authority, it isn't likely to happen soon.

The president's case has been bolstered by last weekend's decision in Chile by the U.S. and 33 other North and South American nations to begin talks toward a hemisphere-wide, free-trade area. At some point after the talks begin, Washington could find itself out in the cold without "fast-track" authority, which permits the president to negotiate trade pacts that Congress can approve but not amend.

The prospect of the rest of the hemisphere moving ahead with trade agreements without the U.S. should make a compelling case in Congress for fast track, some business groups believe. Other nations aren't likely to enter pacts knowing Congress could amend any deal made by the administration.

"The idea that the U.S. could be excluded from actual negotiations taking place creates a different environment," says David Hirschmann, managing director in charge of Western Hemisphere affairs at the U.S. Chamber of Commerce. Last year, Mr. Clinton abandoned the fight for fast track when he failed to muster support. Meanwhile, regional groups in South America have moved ahead with pacts that exclude the U.S.

Despite Mr. Clinton's promise last week to renew the fast-track campaign, the administration isn't expected to begin a big push soon. There is little enthusiasm for new trade pacts. And the administration has other international items before Con-

gress, principally winning approval to expand the U.S. contribution to the International Monetary Fund.

Democratic lawmakers and Clinton economic officials talk of a "tacit agreement" not to bring up fast track this year so Democrats can unite around the administration's request for IMF funding. To win IMF votes, the administration had to forgo issues such as fast track that would split the House Democratic caucus.

Many Republican lawmakers who supported fast track last year have little faith the president will make a strong fight this year. "We sincerely hope the president has a plan to get fast track through Congress," says an aide to GOP Rep. David Dreier of California. "But unfortunately, we haven't seen anything of the sort from this administration, and its lack of leadership on free trade over the past few years doesn't give us much hope at this point."

Last year, fast-track foes, including organized labor, made the case that expanded trade cost American jobs. With the U.S. trade deficit swelling to record levels, there is a broad perception that international trade hurts the economy. In a poll by The Wall Street Journal and 16 newspapers in Latin America, conducted by RAC&MORI International, a Princeton N.J., pollster, 59% of Americans said they opposed fast track. Although nearly half said they supported a hemisphere-wide trade zone, 36% opposed it.

Some Democrats hope that if they deliver on the IMF vote, Mr. Clinton might respond by attaching labor and environmental standards to fast track. But business, which backs both fast track and the IMF bill, opposes such standards.

New York Brokerage Firm Faces Inquiry On Possible Small-Stock Trading Abuses

By PAUL BECKETT
Duke Jones Newsletter

WASHINGTON — In the latest crack-down on possible abuses in trading small stocks, New York state and city authorities have begun inquiries into Manhattan brokerage firm Duke & Co. that could result in criminal charges against the firm, its principals, or brokers.

The New York state attorney general's office is "investigating Duke & Co. in both a civil and criminal context," said Andrew Kandel, chief of the office's bureau of investor protection and securities.

And the Manhattan district attorney's office, which pursues only criminal prosecutions, earlier this month executed a search warrant to seize trading documents from the firm, according to a copy of a letter from Duke's lawyers. Prosecutors continued their inquiries last week, according to people who were contacted.

A spokeswoman for the district attorney's office said she "could neither confirm nor deny anything at this time." An attorney for Duke declined to comment. The brokerage firm has consistently denied wrongdoing.

The probes come on top of civil investigations into the firm's practices by the Securities and Exchange Commission, the National Association of Securities Dealers and state securities regulators. They are looking into possible trading and sales-practice abuses by Duke in three small stocks that the brokerage firm took public in 1995 and 1996: Renaissance Entertainment Corp., Paravant Computer Systems Inc. and Sel-Leb Marketing Inc.

The regulatory barrage, nonetheless, has left some former Duke customers frustrated because the only significant enforcement action to result from the investigations so far is the filing of administrative complaints by some state regulators.

In the meantime, according to allegations contained in private arbitration claims against the firm, Duke has lost investors millions of dollars through conduct that regulators themselves said is filled with red flags of securities fraud. And now investors fear it may be too late: The brokerage firm has shut down its retail operations, its offices are shuttered, and many of its brokers are already working elsewhere.

"More action should have been taken," said Robert Banks, a Portland, Ore., attorney who represents an investor who lost more than \$500,000 because of Duke's alleged misconduct in trading small stocks. "Based on what I've seen, I would have to give the regulators a pretty low rating: unsatisfactory."

Spokesmen at the NASD and the SEC declined to comment. Regulators privately bristle at any suggestion of foot-dragging. They note that cases involving alleged abuses in "microcap" stocks are resource-intensive and difficult to prove.

But in an interview earlier this year, Duke officials cited the length of time the investigations had taken without yielding a case as evidence that there was no

wrongdoing at the firm.

"In this regulatory environment, if they'd found excessive markups by now, there would have been an SEC action," said Gregg Thaler, Duke president. "We're talking almost two years."

Justices Decline To Review Case Of Murder Manual

By EDWARD FELSENTHAL
Staff Reporter of THE WALL STREET JOURNAL
WASHINGTON — The Supreme Court cleared the way for a trial in a case seeking to hold the publisher of a murder manual liable for three killings.

The justices without comment yesterday declined to review a ruling by a federal appeals court that the First Amendment doesn't protect the publisher from civil claims that it aided the 1993 murders. The victims' families filed the case against Peder Lund and his mail-order publishing house, Paladin Press of Boulder, Colo. In the early 1980s, Paladin published "Hit Man: A Technical Manual for Independent Contractors," which was used by a convicted assassin.

The case pits victims-rights advocates against media organizations and civil libertarians, who argue that the suit could jeopardize free speech and freedom of the press.

Judges have typically rejected claims against publishers and production companies involving crimes committed by people who mimic what they have read about or seen depicted in movies and television. But the appeals court suggested that the Paladin case was different because the book was intended to provide step-by-step training for assassins.

In 1995, Lawrence T. Horn was convicted of hiring James Perry to murder his ex-wife, Mildred Horn, and their handicapped son, Trevor, so that Mr. Horn could inherit a \$2 million trust fund intended for the boy. The boy's nurse, Janice Saunders, also was killed. Mr. Perry was convicted of the murders after a trial at which prosecutors alleged that the book provided the blueprint for the murders. Mr. Horn was sentenced to life in prison; Mr. Perry was sentenced to death and is on death row in Maryland.

The victims' families then sued Paladin and Mr. Lund in federal court in Greenbelt, Md., alleging the book aided the murderers, but the trial judge dismissed the case on First Amendment grounds. Last year, the U.S. appeals court in Richmond, Va., reinstated the case. The appeals court said the book lacked "the kind of ideas for the protection of which the First Amendment exists" as well as "any even arguably legitimate purpose beyond the promotion and teaching of murder." (*Paladin vs. Rice*)

Fruit
Juice

TO TOM FRIEDMAN

FROM BILL SCHULTZ



NEWS RELEASE

NATIONAL FOOD PROCESSORS ASSOCIATION • 1401 New York Ave., NW • Washington, DC 20005

FOR IMMEDIATE RELEASE
April 20, 1998

Contact: Timothy Willard (202-637-8060)
Adele Logan-Galen (202-639-5919)

FDA PROPOSALS FOR JUICE SAFETY REGULATIONS "SHOULD MANDATE PASTEURIZATION OR EQUIVALENT PROCESS," SAYS NFPA

Washington, D.C. -- Proposed regulations governing the safety of fruit and vegetable juices -- which the U.S. Food and Drug Administration (FDA) is expected to announce this week -- "should require that all juices be pasteurized or otherwise treated to ensure their safety," said Dr. Allen Matthys, Vice President of Regulatory Affairs for the National Food Processors Association (NFPA).

"NFPA shares FDA's goal of taking effective measures to further enhance the safety of the U.S. food supply," Dr. Matthys noted. "However, it is our strong belief that, unless FDA mandates pasteurization or an equivalent process for all juices -- not just most juices -- this rule will not be successful in advancing food safety in this country."

"The processed food industry has been a pioneer in the development and use of effective food safety technologies," Dr. Matthys commented. "Heat treatment of juice destroys *E. coli* O157:H7 and other pathogenic microorganisms of public health concern. It is our overriding position that juice or juice ingredients should receive heat pasteurization or an equivalent process sufficient to render these products free of dangerous microorganisms."

The FDA proposed regulations -- while stating that most juice products must be pasteurized or otherwise treated to kill disease-causing organisms -- do not require pasteurization or heat treatment for all juices, as NFPA has urged. Prior to the effective date of the proposed regulations, the Agency intends to require warning labels on unpasteurized products, to alert consumers that unpasteurized juices can contain bacteria that pose a special risk certain individuals, particularly children and older Americans.

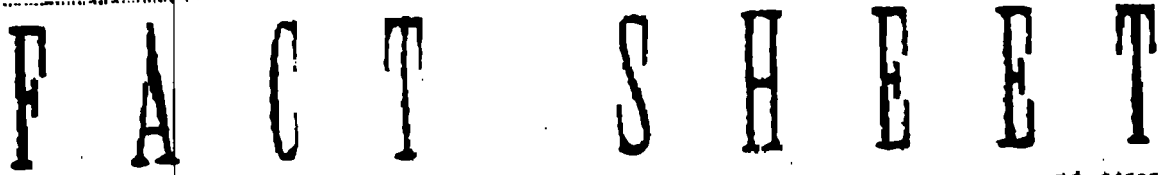
-M-O-R-E-

"It is important for consumers to know that the vast majority of juices sold in the United States -- more than 98 percent -- have been pasteurized or otherwise heat treated, and that those juices can be purchased and consumed with confidence," Dr. Mathys pointed out. "For example, all shelf-stable juices -- those that do not require refrigeration prior to opening -- have been heat processed. Frozen concentrated juices also are produced from ingredients that have been heat processed. And many refrigerated juices also have been pasteurized. Consumers can check with the retailer or manufacturer if they have questions."

Mathys stated that "NFPA looks forward to closely examining FDA's proposal, and we will work the Agency to provide assistance in helping to formulate a final rule that truly helps to enhance the safety of our nation's food supply."

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NFPA is the voice of the \$430 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. For more information, or to arrange an interview with an NFPA spokesperson on this issue, contact Timothy Willard, NFPA's Senior Director of Communications, at (202) 637-8060, Adele Logan-Galen, Director of Media Relations and External Affairs, at (202) 639-5919, or visit NFPA's Website at www.nfpa-food.org.



JUICE PRODUCTS

A: No, the FDA does not require juice or juice products to be pasteurized at this time. However, the FDA does require milk or milk products intended for sale in interstate commerce to be pasteurized. NFPA members have requested that the FDA require that juices be pasteurized or otherwise treated to destroy pathogenic bacteria.

Juice Products...page two

Q: If I purchase unpasteurized juice is there anything I can do to make it safer?

A: Juice that is purchased fresh should be heated to 160° Fahrenheit to ensure that harmful pathogens are destroyed. For consumers who do not have a thermometer, bringing the product to a boil (212° F) is more than adequate.

Q: What is NFPA's position regarding juice pasteurization?

A: NFPA's overriding position is that juice or juice ingredients should receive heat pasteurization or an equivalent process sufficient to eliminate microorganisms of public health significance. Moreover, NFPA wants to stress that the juice processing industry has provided safe juice products for decades.

Q: What percentage of juices available today have been pasteurized?

A: According to the FDA, fresh juice producers constitute approximately two percent of juice manufacturers nationwide; thus, about 98 percent of juice sold has been heat-treated.

The National Food Processors Association is the scientific trade association representing the \$430 billion food processing industry. With 80 scientists in three laboratories, NFPA is the leading authority on food science and food safety for the food industry. For more information, visit our website at: www.nfpa-food.org, or call Adelle Logan-Galen, Director of Media Relations at (202) 639-5919.

Fruit
Juices - how

→ Retail vs Manufactures

→ 100,000 gallons

Should exempt

Roadside vs. grocery

~~Label~~

→ Label

Roadside stands

→ ask for country

① If U don't sell Apple juice
\$0,000 off price

② Sell 100 + 100,000 OJ → labeling

FDA to Propose Juice Safety Regulations

Aim Is to Prevent Contamination; Some Products Would Get Warning Labels

By JOHN F. HARRIS
Washington Post Staff Writer

The Clinton administration this week will announce new regulations designed to improve the safety of juices, in particular fresh-squeezed varieties such as the bacteria-tainted apple juice that caused one death and widespread illness in western states in 1996.

While many consumers buy expensive fresh-squeezed juices on the belief that they are more healthful, food safety experts say the opposite often is true if these juices have not been pasteurized or undergone other procedures to kill disease-causing organisms.

The Food and Drug Administration this week will seek public comment on proposed new rules that would require nearly all juice-makers to implement these procedures, administration officials said. In the interim, the agency intends to require warning labels on unpasteurized juices to alert consumers that the products can contain hazardous bacteria and pose a special danger to children, the elderly or people with suppressed immune systems.

Contaminated juices are not a widespread public health problem. The vast majority of juices—some 98 percent—on the market are already pasteurized, regardless of whether they are fresh or made from concentrate, according to government and industry officials.

Even so, in recent years considerable attention has focused on the 2 percent that is not treated. In perhaps the most notori-

ous episode, a 16-month-old Colorado girl died and some 70 other people in Washington and other states became severely ill in 1996 by drinking Odwalla brand apple juice.

The juice had become infected with an especially toxic strain of *E. coli* bacteria, causing kidney failure and heart damage in the girl, Anna Gimmetstad of Evans, Colo.

Under the proposed FDA rules, recently endorsed by senior White House officials, all juice producers would be required to set up procedures to prove to inspectors that they are monitoring health concerns and have sharply reduced the level of microbes that typically are found in untreated juice.

Administration officials said those juice bottlers who already pasteurize their products would most likely have little trouble meeting the new standards, although they must also demonstrate that they are monitoring for pesticide residue and glass shards in their products.

The new regulations also would allow for exceptions. Stores that sell juice for drinking on the premises, such as juice bars, would not be affected. Grocery stores and other retail outlets that press their own juice for sale on the premises but not for broader distribution would not have to pasteurize, but their products would have to carry the warning labels.

President Clinton has put an emphasis on food safety issues over the past two years, beginning in the 1996 campaign when he and his political advisers were

searching for issues that resonated with average voters and were looking for ways to counter conservative claims that the federal government should be scaled back sharply.

The new juice safety procedures mirror those already put in place by the FDA for seafood, which is also under that agency's jurisdiction.

The Agriculture Department, which regulates beef and poultry, last year announced new rules designed to reduce contaminated meat.

The new regulations, after being published in the Federal Register, may be revised after a public comment period, but administration officials said they expect them to be in place by the summer.

Gene Grabowski, a spokesman for the Grocery Manufacturers of America, said his organization's members would be looking closely at the details, but he predicted little opposition since most juice producers already pasteurize their products.

Caroline Smith Dewall, director of food safety for the Center for Science in the Public Interest, said the new rules are "critically needed."

The assumption until not long ago, she said, was that juices were acidic enough to prevent bacteria from growing. The Odwalla case and others like it in recent years have shown this is not the case.

Without the new rules, she said, "we'll reach the point where we'll have to keep children and elderly from drinking cider."

MONDAY, APRIL 20, 1998
The Washington Post

Fruit
Juices

FDA Proposed Juice Regulation

Proposal

- ✓ - Require severe warning labels now
- ✗ - Apply HACCP over next 3 years, including required pasteurization
- ✓ - Would apply not only to apple juice, but all juices
- ✗ - Would also apply to restaurants and stores (both warnings and procedures)

Pros

- ✓ - Strong statement in favor of food safety
- ✓ - Extends application of HACCP method (better way to regulate) | define parameter

Cons

- Would eliminate almost all fresh-squeezed juice from the market
- Mom & pop cider manufacturers will see as being forced out of cider business
- Would require warning on restaurant menus, which we don't do now. May be seen as overregulating.
- Applies controls in an industry where the problems have been more limited than seafood or poultry
- Industry may see as "camel's nose" for regulation of all fruits & vegetables

Pasteurization Requirement ? / Regulatory Process.
= Regulatory Bifurcation

ONE kid even too much

AP story -> Odwalla

Let me be clear: this will NOT
Ten year old Lemonade stand

Fruit Juices - GW
FDA'S JUICE PROPOSAL

o In response to numerous past incidents of illness and death associated with consumption of untreated fruit and vegetable juices (the most visible being the e-coli outbreak from fresh Odwalla apple juice in 1996), FDA has prepared 2 proposals to address the safety of juices:

- One would require the use of Hazard Analysis Critical Control Points (HACCP) controls by juice manufacturers; HACCP has been mandated already by FDA for seafood and USDA for meat and poultry; it is considered the state-of-the-art quality control system.

- The second proposal would require that juices that have not been treated to reduce disease causing pathogens (e.g., pasteurization) be labeled with a warning statement about consuming untreated juice (aimed principally at the very young, the elderly, and those with weak immune systems).

o FDA's regulation was submitted to OMB on 2/3/98, with the goal of publication by April 15 (so that a final rule could be promulgated in time to have the labeling requirement in effect for this fall's apple juice season).

o OMB has objected to the FDA proposal in three general categories--numerous minor editorial changes, requests for modifications in FDA's economic impact analysis, and 2 major policy issues.

o The 2 policy issues are the most serious obstacles to publication of the proposal. They can be summarized as follows:

- 1) FDA's proposal: The proposed regulations would require that all juice manufacturers implement HACCP controls by late 1999 (1-2 yrs. later for small businesses); HACCP controls cover such things as elimination of bacterial, chemical (e.g., pesticides), and physical (e.g., glass shards) hazards. Until such controls are in place, manufacturers would be required to label their juice with a warning for consumers of the health risks.

OMB's Passback: In general, OMB proposes that juice manufacturers have a permanent choice between warning consumers or eliminating the hazards. [For non-apple juices, OMB proposes giving manufacturers the permanent option between implementing a HACCP system, pasteurizing (or otherwise achieving a specified performance standard for bacteria reduction), or labeling. For apple juice, OMB proposes giving manufacturers the permanent option of implementing a HACCP system or labeling.]

FDA Comment: Under OMB's proposal, there is no incentive for manufacturers to ever adopt HACCP controls. Indeed, all manufacturers could simply label juice that was hazardous. Non-apple juice manufacturers would also have the option of simply pasteurizing, which would control only for bacteria. HACCP systems control not only for bacteria but also for chemical and physical hazards (which also pose risks to consumers).

- 2) **FDA's Proposal:** Retailers, such as juice bars, restaurants, and many roadside cider stands, are exempt from HACCP requirements, but not from the labeling requirement.

OMB's Passback: OMB proposes to exempt retailers from both HACCP and labeling.

FDA's Comment: OMB's proposal would remove the only public health protection at the retail level in FDA's proposal. The little retail operations are one of the agency's greatest concerns, so exempting them from the labeling as well as the HACCP requirement is not consistent with protecting the public from unsafe juice.

