cases. For the unknown pathogen we multiplied 6 annual laboratory-confirmed cases by 100 for an estimated 600 total juice-related cases.

Among reported cases of the four pathogens, *E. coli* O157: H7 has led to the most severe human health consequences, including hemolytic uremic syndrome and death. The most severe reported juice-related Salmonella cases have led to hospitalization. Cases of *C. parvum* and *B. cereus* have caused gastrointestinal and other symptoms, but have not required hospitalization. The severity of unreported cases is uncertain; in this preliminary investigation we assumed that that the severity of unreported juice-borne illnesses was similar to the severity of all foodborne illnesses. For all foodborne pathogens, the average severity of illnesses associated with *E. coli* O157: H7 is greatest, followed by the illnesses associated with *Salmonella*. Foodborne *C. parvum* and *B. cereus* both lead to milder symptoms.

The other hazards -- mostly physical and chemical -- that have been found in juices have been sporadic and associated with fewer cases than the microbial pathogens.

Illnesses and deaths in four recent outbreaks associated with juice products have demonstrated that juices can present serious human health hazards. The principal purpose of this preliminary investigation is to separate what we know from what we do not know about the hazards associated with juices. We will use what we know to make some preliminary inferences about what we do not know. These inferences are not intended to be the final word on the morbidity and mortality associated with the consumption of fruit and vegetable juices. On the contrary, the study of the hazards associated with juices is ongoing and will change as we accumulate new data and other information.

Most hazard assessments are performed for a single hazard, such as a pesticide or a specific microbial pathogen. The hazard assessed may even be limited to a single food or product. This study of the hazards associated with juices will concentrate on microbial pathogens in fruit and vegetable juices, but will also include physical and chemical hazards. The organization of the report is as follows:

I. Description of the Product
II. Consumption
III. Description of the Production Methods: What Can Go Right
IV. Potential Introduction of Hazards into Juice Products: What Can Go Wrong
V. The Level of Contamination and the Probability of Illness: Evidence that Something Has Gone Wrong
VI. Human Health Effects
VII. Not Heat-Treatable Hazards
VIII. Summary

The most important health hazards recently associated with juices have been microbial pathogens; the framework for this investigation will therefore be based on microbiological hazards. The framework will be modified as necessary to account for other types of hazards, including chemical and physical hazards.

I. Description of the Product

The products encompassed by this investigation include juices, drinks, and nectars made from soft fruit (e.g., berries, cranberries, and currants), stone fruit (e.g., prune, apricot), citrus fruit, pome fruit (e.g., apple, pear), mixed fruit, fruit seed or pit (e.g., coconut), tropical fruit (e.g., guava, mango), vine fruit (e.g., grape), any other fruit, beans-peas-corn, fruits-used-as-vegetables (e.g., tomato), leaf and stem vegetables (e.g., celery), root and tuber vegetables (e.g., carrot), and mixed vegetables. The various products are sold in cans and paper, plastic, or glass containers. Products are either shelf-stable, frozen, or refrigerated.

II. Consumption

We estimated the annual consumption of all fruit and vegetable juices and juice drinks. We based the estimates on several sources; the table below shows the sources of data and how we used them.

Source of data	Description	Uses
Putnam and Alehouse (1997)	U. S. Department of Agriculture disappearance data	Total juice consumption; part of calculation of consumption of non-heat-treated orange juice
U. S. Department of Agriculture (1995), *Continuing Survey of Food Intakes of Individuals, 1989-1991.*	Consumer survey data	Percentiles of juice consumption; consumption of juices by different age groups; corroboration of disappearance estimates of consumption
Nielsen SCANTRACK	Results from supermarket sales by bar codes	Fraction of total juice consumption accounted for by non-heat-treated orange juice; lower-bound

		estimated consumption of non-heat-treated apple juice and cider
U. S. Apple Association (1997a; 1997b)	Survey of apple cider processors	Consumption of non-heat-treated apple juice and cider

We used the disappearance data in preference to other sources, which we used mainly for information not contained in the disappearance data. Annual juice consumption can be measured and reported in gallons, liters, or servings, and can be characterized as per person, per juice drinker, or total. Although the data available and the question to be answered determined how we characterized various aspects of juice consumption, we used total servings as the principal measure of annual exposure.

We expected the distinction between heat-treated and non-heat-treated juices to matter more than any other for the morbidity and mortality associated with juices. We therefore estimated both total juice consumption and the consumption of non-heat-treated juices.

A. TOTAL CONSUMPTION OF FRUIT AND VEGETABLE JUICES

The Economic Research Service of the U. S. Department of Agriculture (Putnam and Alehouse 1997) estimates annual food consumption as the residual in the food supply and food use balance sheet. Total available food supply is the sum of production, beginning inventories, and imports. The measurable uses of food commodities include exports, industrial uses, seed and feed, and closing (or end-of-year) inventories. The difference between available supply and measurable uses is called food disappearance.

The use of food disappearance to estimate human food consumption has some shortcomings. The assumption that people consume all non-measured food commodities is wrong, because much food is wasted or fed to pets and other animals. Moreover, the estimated measurable uses of food commodities may miss some non-food uses. Food disappearance should therefore be regarded as an upper bound on the consumption of most foods. For juices, however, the difference between the upper bound represented by disappearance and the true level of consumption is probably small, because juices do not have non-food uses. In this investigation, we used the disappearance data as the principal estimate of annual consumption of fruit and vegetable juices and drinks.

The consumption (or disappearance) per person of the major fruit juices (single strength equivalent: orange, grapefruit, lemon, lime, apple, grape, pineapple, prune) was 8.7 gallons in 1995 (Putnam and Alehouse 1997). The disappearance data do not contain separate estimates for berry, pear, plum, apricot, coconut, and tropical fruit juices, but the consumption of these juices is likely to be quite small. Vegetable juice (mainly tomato and tomato-based mixed juices) consumption was 0.3 gallons per person, for total juice consumption of 9.0 gallons or 34.1 liters (9.0 gallons × 3.785 liters per gallon) per person per year. Total annual consumption of juice products (based on a population of 260 million) was therefore 2.3 billion gallons (260 million × 9.0 gallons), or 8.9 billion liters (see table 1). In addition to juices, Americans consumed 7.8 gallons per person of fruit drinks (including flavored non-carbonated drinks, cocktails, and ades), for a total juice drink consumption of 2 billion gallons or 7.7 billion liters.

The great variety of juices and juice products consumed may give the misleading impression that American juice consumption is extremely varied. As table 1 shows, orange juice consumption -- 5.45 gallons per person in 1995 -- accounted for 60 percent of all juice consumed. Americans consumed 1.79 gallons of apple juice per person -- 20 percent of all juice consumed. The Continuing Survey of Food Intakes by Individuals gave a similar picture of juice consumption. In the survey for 1989-1991, orange juice accounted for 55 percent and apple juice for 17 percent of all eating occasions for juices. Southgate, Johnson, and Fenwick (1995) estimated orange juice to be 55 percent and apple juice to be 19 percent of total juice consumption. Orange and apple juices therefore account for the greater part of total juice consumption.

Juice and juice drink consumption can be put in perspective by comparison with the consumption of other beverages. In 1995, the average American consumed 24.4 gallons of milk, 11.6 gallons of bottled water, 20.5 gallons of coffee, 8.7 gallons of tea, 51.2 gallons of carbonated soft drinks, and 25.1 gallons of alcoholic beverages (Putnam and Alehouse 1997). Fruit juices and fruit drinks combined accounted for more than 10 percent of all major beverage consumption (see table 2).

The U. S. Food and Drug Administration's (FDA) serving size for fruit juices and fruit drinks (and all other beverages) is 8 fluid ounces (240 milliliters). The serving size represents the amount customarily consumed per eating occasion for fruit and vegetable juices and juice drinks. The FDA juice serving size implies that total juice servings in 1995 were 37 billion (2.3 billion gallons ÷ 0.0625 gallons per serving). For juice drinks, the total number of servings was 32 billion servings (2.0 billion gallons ÷ 0.0625 gallons per serving).

The U. S. Department of Agriculture's Continuing Survey of Food Intakes by Individuals for 1989-1991 provides another way to estimate the annual consumption of juices. We used it to check the plausibility of the estimates derived from the disappearance data. The survey counted 219,181 eating occasions for juice products over a 3-day period. Each weighted response represented on average 1000 people. We estimated total juice drinking occasions per year to be 219,181 × 1,000 × 121 = 26.5 billion. If each person consumed (on average) 8 ounces per eating occasion, then the total amount consumed was 1.7 billion gallons (26.5 billion × 0.0625 gallons). The annual amount consumed per person would be 6.9 gallons (1,660,000,000 gallons ÷ 248,000,000 people). This estimate is lower than the 9.0 gallons estimated from the disappearance data partly because fruit juice consumption per person rose 13 percent between 1989-1991 and 1995. In 1989-91 juice disappearance averaged close to 8 gallons per person. In addition, as we pointed out above, the disappearance of fruit and vegetable juices overstates consumption because it is the residual left after other uses have been measured. Any measurement error or waste will be counted as juice consumption. Finally, the survey understated consumption because it counted an eating occasion with multiple servings as a single serving.

We believe, then, that juice consumption as estimated from the Continuing Survey of Food Intakes by Individuals for 1989-1991 and the disappearance data (Putnam and Alehouse 1997) give roughly consistent estimates of juice consumption. Because it was more recent, we relied on the disappearance data for our overall estimates of juice consumption. The disappearance data, however, did not tell us anything about the distribution of juice consumption -- all it told us was the annual per capita consumption of the leading juices. To estimate the distribution of juice consumption, we used the Continuing Survey of Food Intakes by Individuals for 1989-1991.

According to the survey, approximately 40 percent of the population ("eaters") consumed at least one serving of fruit or vegetable juice over a 3-day period. We will use that fraction as a lower-bound estimate of the number of regular consumers. For these juice drinkers, mean annual consumption was 16 gallons. Median annual consumption equaled 12 gallons. Other points of the distribution of consumption included the 25th percentile consumption equal to 8 gallons, the 75th percentile consumption equal to 22 gallons, and the 90th percentile equal to 32 gallons. According to the survey, the amount of juice consumed by relatively heavy juice drinkers remained low. Two standard FDA servings of juices per day (16 ounces, or 46 gallons per year) would have put an individual above the 95th percentile consumer in the survey. This result, however, may partly reflect the survey's under-count of the number of servings per eating occasion.

The Continuing Survey of Food Intakes by Individuals also showed that children and the elderly consumed a disproportionate amount of juices. Children under the age of 6 made up 9 percent of the population at the time of the survey, but consumed 16 percent of juices. Adults 60 and over made up 17 percent of the population, but consumed 20 percent of juices. Fruit juice accounts for 50 percent of all fruit servings consumed by children (Dennison 1996).

B. NON-HEAT TREATED JUICES

We estimated the consumption of non-heat-treated juices by combining estimates of total consumption or production with estimates of the market share of non-pasteurized juices. The two main products in the non-heat-treated category are fresh orange juice and natural (or fresh) apple cider or juice. We did not have direct estimates of the consumption of non-heat-treated juices. We estimated consumption of non-heat-treated citrus juice indirectly by combining information from supermarket sales data with disappearance data. Because the supermarket sales data did not list non-heat-treated apple juice as a separate category, we relied on industry production data on apple juice and cider for our best estimate of consumption.

Orange juice. According to the Nielsen SCANTRACK data, by volume fresh squeezed citrus juices accounted for 0.5 percent of all fruit juices sold in 1996. We assumed that nearly all of that was orange juice (some grapefruit juice is sold fresh-squeezed). The annual amount of fruit juice consumed was approximately 9.0 gallons per person in 1995 (see table 1); the amount of non-pasteurized orange juice per person would therefore be 0.05 gallons (0.005 × 9.0 gallons). The total annual amount of non-pasteurized orange juice consumed would be 11,700,000 gallons (0.005 × 9.0 gallons per person × 260,000,000 persons). With the FDA serving size of 8 ounces, the total number of servings of fresh-squeezed orange juice would be 187 million per year (11.7 million gallons ÷ 0.0625 gallons per serving).

Apple juice and cider. The Nielsen SCANTRACK survey does not distinguish between heat-treated and non-heat-treated apple cider. According to the Nielsen 1996 data, 16.4 million gallons of cider required refrigeration. Because many of the refrigerated products sold as apple cider were pasteurized, this estimate may have overstated the amount of non-heat-treated apple cider sold. For two reasons, however, the Nielsen total for refrigerated apple cider more likely understated the amount of non-heat-treated apple juice and cider. First, the survey did not include small grocery stores and other retail stores where refrigerated cider was sold. Second, the total excluded non-heat-treated apple juice. The survey recorded sales of 83 million gallons of refrigerated apple juice, with some unknown proportion not pasteurized. Sales of refrigerated apple cider may therefore underestimate total sales of non-heat-treated juice and cider. The Nielsen survey results served as a lower-bound estimate of the consumption of unpasteurized cider and juice. The lower-bound annual amount of unpasteurized apple cider and juice consumed per person would therefore be 0.063 gallons, or 8 ounces (16,400,000 gallons ÷ 260,000,000 persons) -- the FDA serving size. The consumption per person, then, would be approximately one serving per person per year, or 260 million servings.

Data supplied by the U. S. Apple Association provided a more complete estimate of the consumption of non-pasteurized apple cider (U. S. Apple Association 1997a). The association identified 1,049 producers of apple cider in the United States. The association distributed 918 surveys to apple cider processors and received 465 responses (51 percent), although not all surveys were returned complete. Of those cider producers in the sample, 97 percent did not pasteurize their product. The producers who did pasteurize, however, were all in the largest sales category. By volume and sales, pasteurized apple cider accounted for much more than 3 percent of output, but we do not know how much more. The processors in the U. S. Apple Association survey who reported engaging in interstate commerce also came disproportionately from the large producers.

The survey gave ranges of output by gallons for apple cider for 409 respondents (88 percent). The largest category by number of firms consisted of 187 small producers who each sold less than 5,000 gallons of apple cider per year. The smallest category by number of firms contained the 7 producers who each sold more than 500,000 gallons per year and probably accounted for a majority (by volume) of cider sales. We estimated total production for the 409 respondents by assigning mean volumes of the range in each category. We assigned all processors in the under 5,000 gallons category an annual output of 2,500 gallons; other assigned outputs included 7,500 gallons for the 5,000 to 9,999 gallons range, 30,000 gallons for the 10,000 to 49,999 range, 75,000 gallons for the 50,000 to 99,999 range, 300,000gallons for the 100,000 to 499,999 range, and 750,000 gallons for the 500,000 to 999,999 range. Two processors produced more than one million gallons per year (U. S. Apple Association 1997b). The survey gave us no further information, but other sources indicated that at least one large processor produced approximately 4 million gallons per year. We used the range 1,000,000-4,000,000 gallons for the largest output category and assigned each of the two largest survey respondents outputs of 2,500,000 gallons, the midpoint of the range. Under these assumptions, we estimated that the survey respondents produced a total output of 20 million gallons ((187 × 2,500) + (50 × 7,500) + (135 × 30,000) + (12 × 75,000) + (18 × 300,000) + (5 × 750,000) + (2 × 2,500,000)).

The survey respondents produced an estimated 20 million gallons of apple cider, and the response rate to the survey was approximately 50 percent. If the size distribution of non-respondents was the same as respondents, total production equaled 40 million gallons (2 × 20 million gallons). The large interstate producers were more likely to pasteurize their product. Of the 51 interstate producers who responded to the survey, 7 pasteurized and 4 planned to do so in the future (U. S. Apple Association 1997b). In the largest sales category (annual sales greater than $100,000) one half of respondents reported pasteurizing (or had plans to do so in the future). We assumed that all of the firms that were pasteurizing their product came from the three largest output categories, and that half of the firms in those output categories pasteurized their product. Under those two assumption, pasteurizing firms produced 7 million gallons ((18 × 300,000 ÷ 2) + (5 × 750,000 ÷ 2) + (2 × 2,500,000 ÷ 2)), or approximately 35 percent of the survey respondent's output. If the percentage pasteurizing was the same for non-respondents as for respondents, then the total production of pasteurized apple cider was 14 million gallons. Under these assumptions, the total amount of unpasteurized cider would be 26 million gallons (40 million gallons - 14 million gallons). The total number of servings would be 416 million per year (26 million gallons ÷ 0.0625 gallons per serving). Consumption per person would be 0.1 gallons (26 ÷ 260,000,000). The amount exceeded what we estimated from the Nielsen data, probably because the U. S. Apple Association surveys implicitly included more retail outlets than did Nielsen.

Total. We estimated the annual consumption of non-heat-treated orange and other citrus juices to be 11.7 million gallons, or 44 million liters. Annual consumption per person would be about 0.05 gallons. The lower-bound estimated consumption of non-heat-treated apple juice or cider, 16.4 million gallons (62 million liters), came from Nielsen SCANTRACK and failed to include large parts of the market. We therefore chose the higher estimate, 26 million gallons (98 million liters), from the U. S. Apple Association surveys as the preferred estimate of the consumption of non-heat-treated apple juice or cider. We estimated annual consumption per person to be 0.1 gallons per person.

We added the higher apple cider estimate to the Nielsen orange juice estimate to estimate the annual consumption of all non-heat-treated fruit and vegetable juices. The sum, 38 million gallons, (0.15 gallons per person) represented about 1.7 percent (38,000,000 ÷ 2,300,000,000) of total juice consumption. The total number of servings of non-heat-treated juice would be approximately 600 million servings (187 million servings of orange and other citrus juice + 416 million servings of apple juice or cider).

High-risk consumers. We did not find direct estimates of the consumption of non-heat-treated juices by children and old people. As a proxy for non-heat-treated apple juice and cider, we used cider consumption from the Continuing Survey of Food Intakes by Individuals. According to the 1989-1991 survey, children consumed a disproportionate amount of apple cider. Children under the age of 6 made up 9 percent of the population at the time of the survey, but consumed 16 percent of cider. Adults 60 and over made up 17 percent of the population and consumed 17 percent of apple cider.

The survey did not list the consumption of fresh orange juice as a separate category, but did list the consumption of fresh grapefruit juice, which we assume to be non-heat-treated. Children under the age of 6 consumed little fresh grapefruit juice, accounting for less than one-half of one percent of total consumption. Adults 60 and over, by contrast, accounted for more than 48 percent of fresh grapefruit juice consumption -- close to triple that group's population share.

III. Description of the Production Methods: What Can Go Right

As table 3 illustrates, the production of juices is remarkably similar across products. Obtaining fruit and vegetable juice from fruits and vegetables requires up to 12 processing steps, many with several different processing possibilities. The 12 steps are:

1) Growing
2) Harvesting
3) Washing and culling
4) Extraction of juice
5) Pressing to separate juice from remaining solids
6) Clarification and filtration to remove various impurities
7) De-aeration (removes air bubbles)
8) Heat treatments (includes pasteurization) and other anti-microbial treatments
9) Concentration
10) Refrigeration or preservatives
11) Reconstitution of juice from concentrate
12) Packaging

Some products go through all 12 steps; others, such as unpasteurized fresh juices, go through fewer steps. The major unpasteurized commercial products are apple cider (which is unfiltered apple juice), filtered apple juice, and fresh orange juice. Most juice products apparently go through some type of heating stage to inactivate microorganisms or oxidative enzymes.

What follows are short descriptions of different types of juices -- how the fruits and vegetables are harvested, processed, and turned into juice.

A. APPLE JUICE

Varieties. The 15 commercially most important varieties have historically been Red Delicious, Yellow Delicious, Macintosh, Rome Beauty, Jonathan, York Imperial, Stayman Winesap, Yellow Newtown, Cortland, Rhode Island Greening, Winesap, Northern Spy, Idared, Gravenstein and Granny Smith.

Growing environment. Apples are grown throughout the United States, with Washington, New York, Michigan, California and Pennsylvania being the largest producers (Way and McLellan 1989). Apples are grown both in humid and dry areas, high and low altitudes, warm and cold climates. Most orchards do not use manure as a fertilizer (U. S. Apple Association 1997a). Deliberate livestock grazing is rare; most growers attempt to keep wild animals away from the trees, although it is impossible to keep all wildlife out of orchards. Apples may be sprayed with pesticides in the orchard.

Juice. The definition of apple cider and apple juice differs across regions. Cloudy juice is called cider; thoroughly filtered and clarified juice is called juice. Different definitions exist for products that have undergone some filtering and clarification, but are not clear. In general, the product must be cloudier in New England than in the West in order to qualify as cider.

Most apple cider or juice is a blend of several varieties of apples. Blending enables the producer to achieve the desired balance of acidity, aroma, astringency and sweetness (Downing 1989).

Harvesting. Apples can be harvested by hand or by machine. Hand harvesting is much more common, because mechanical harvesting damages fruit more frequently (Massey 1989). Apples are stored in the processor's yard only for short periods after harvest. Long-term storage takes place in facilities where low temperature (normally -1 to 0°C), adequate ventilation, and a controlled atmosphere (less than 3 percent O_2 and less than 3 percent CO_2) can be maintained. Half of the respondents in a survey of apple cider producers use drops (apples that have fallen to the ground)(U. S. Apple Association 1997a).

Transportation. Apples are packed in 20-pound boxes (Eastern U. S.) or bushel packs (Western U. S.). They are most often transported to processing facilities in open trunks or wagons pulled by tractors.

Washing and inspection of fruit. A bin of apples is usually dumped into water at an inspection station. Some apples are culled and the rest washed in an acid bath of pH 2 or 3; others are dumped into water with 100 ppm chlorine (or higher) (Kupperman 1996). Some apple processors use either brushing or agitation (O'Leary 1993). The apples are rinsed before the juice is extracted (with skin on) and the remaining solids pressed (steps 3, 4, and 5).

Finished product. Nothing further is done to natural cider or juice, except chilling, possible chemical preservation (step 10), refrigeration or freezing (step 10), and packaging (step 12). For heat-treated apple juice, clarification (step 6) and pasteurization (step 8) will be performed. Pasteurization takes 25 to 30 seconds at temperatures that vary between 76.6°C and 87.7°C. Apple juice to be concentrated (step 9) is heated to temperatures of 77 to 93°C for 2 to 3 minutes (Kress 1996). The juice leaves the concentrator at about 70° Brix (70 percent sugar) (Kress 1996). Juice can then be re-constituted. (step 11).

Apple juice is hot-filled at 79 to 91°C into containers and held for 1 to 2 minutes before closing (step 12). Containers are cooled to between 32 and 41°C and stored (Kress 1996).

Imports. Imported apple juice accounts for close to one-half of total consumption (see table 1). Practically all imported juice comes in the form of concentrate (*The Almanac of* *the Canning, Freezing, Preserving Industries* 1996). The imported apple juice comes from all over the world, with Latin America and Europe being particularly important sources.

B. ORANGE JUICE

Varieties. One species of orange, the Sweet Orange, is commercially important in the United States. Sweet Oranges include common (or Valencia), navel, blood, non-acid, and sour oranges. Most orange juice is made from Valencia and navel oranges (Kimball 1991). Domestic oranges are grown in Arizona, California, Florida and Texas (Rebeck 1995).

Juice. Most commercial orange juice is a blend of several varieties. Non-pasteurized, which is mostly fresh-squeezed juice, comes from one variety at a time -- such as early season Hamlin or late season Valencia oranges (Attaway, Carter, and Fellers 1989).

Harvesting and transportation. In Florida, harvesting begins when the fruit reaches the standard for maturity established by the USDA and the Florida Department of Citrus. California does not have mandatory USDA or state standards for maturity. Oranges are harvested by hand or by machine; the fruit is then loaded into trucks that hold 500-550 boxes (90 pounds each) of fruit (Rebeck 1995). Trucks dump oranges onto a ramp where processing eliminates leaves, stems and dirt. Oranges are culled and then put into holding bins.

Washing and inspection of fruit. Conveyer belts move oranges from holding bins to surge bins to roller spreaders and brush washers. The oranges are washed with a detergent and culled again before the orange juice is extracted (with skin off, step 4) and pressed (step 5) (Kimball 1991; Rebeck 1995; Nordby and Nagy 1980). For non-pasteurized juice, the oranges may be chilled to 0.6°C before juice extraction (Attaway, Carter, and Fellers 1989).

Finished product. Nothing further is done to non-pasteurized juice, unless a heat exchanger is used to chill the juice to -1.1°C. Refrigeration (step 10) will be used for preservation; packaging will be in non-hermetically sealed containers (step 12) (Attaway, Carter, and Fellers 1989).

For heat-treated orange juice, filtration, de-aeration, and pasteurization will all be performed. Pasteurization takes about 30 seconds at temperatures between 60°C and 93°C (Rebeck 1995, Nordby and Nagy 1980). Orange juice that is for concentrate is heated to about 81.9°C , although we do not know the period of time for this heat treatment (Rao and Sancho 1993). The juice leaves concentrator at about 65° Brix (65 percent sugar).

Imports. Orange juice (almost all concentrate) is imported from Brazil, Mexico, and other countries. Brazil is the world's leading exporter of orange juice. Imported orange juice accounts for more than 15 percent of consumption (see table 1) (*The Almanac of the Canning, Freezing, Preserving Industries* 1996).

C. GRAPEFRUIT JUICE

Varieties. There are two basic types of grapefruit -- common (or white) and pigmented (or pink). White grapefruit varieties commercially grown in the U. S. are Duncan and Marsh. Pink grapefruit varieties are Flame, Henderson, Ray Ruby, Rio Red and Star Ruby (Kimball 1991).

Harvesting and transportation. In Florida, harvesting begins when fruit reaches maturity standards set up by the USDA and the Florida Department of Citrus. Grapefruit are harvested by hand or by machine; the fruit is then loaded into trucks that hold 500-550 boxes (85 pounds each) of fruit (Rebeck 1995). Trucks dump grapefruit onto a ramp where processing eliminates leaves, stems and dirt. The grapefruit are culled and put in holding bins.

Washing and inspection of fruit. Conveyor belts move the grapefruit from holding bins to surge bins to roller spreaders and brush washers, where the grapefruit are washed with a detergent and culled again before the juice is extracted (skin off, step 4) and solids pressed (step 5).

Finished product. The literature we have surveyed does not contain references to unpasteurized grapefruit juice. We therefore assume that, because grapefruit juice processing and orange juice processing are similar in the steps leading to and including pasteurization, the methods for processing grapefruit juice that does not undergo pasteurization are similar to the methods for orange juice that does not undergo pasteurization.

For heat-treated grapefruit juice, filtration, de-aeration, and pasteurization will be performed. Pasteurization temperatures are between 60°C and 88°C for about 30 seconds (Rebeck 1995; Nordby and Nagy 1980). Although the literature does not say, we assume that grapefruit juice is concentrated at the same temperature as orange juice. The juice leaves the concentrator at about 65° Brix (65 percent sugar).

Imports. Some grapefruit juice (almost all concentrate) is imported from Latin America. Imported grapefruit juice accounts for less than one percent of consumption (see table 1) (*The Almanac of the Canning, Freezing, Preserving Industries* 1996).

D. TANGERINE AND LEMON JUICE

The six varieties of tangerines commercially important in the U. S. are Clementine, Dancy, Kinnow, Lee, Murcott and Nova. Up to 10 percent of tangerine juice can be added to orange juice without declaration or violation of federal standards of identity.

Tangerines to be made into juice are handled and processed in a similar manner to oranges and grapefruit.

Lemon juice is prepared and handled in a similar manner to the other citrus juices (Swisher and Swisher 1980). In certain cases, lemon juice may be crushed and comminuted (minced) (Worrall 1994). Juice that is to be concentrated is usually prepared from unpasteurized or partially pasteurized lemon juice (Swisher and Swisher 1980).

Imports. Lemon juice (almost all concentrate) is imported from Latin America. Imported lemon juice accounts for more than 28 percent of consumption (see table 1) (*The Almanac of the Canning, Freezing, Preserving Industries* 1996).

E. GRAPE JUICE

Varieties. There are 4 classes of grapes: hybrids of native northeastern grapes, European grapes, southern and southeastern Muscadine grapes, and French hybrids (McLellan and Race 1995). Most grape juice is made from the Concord grape, a northeastern hybrid. The rest of this discussion will refer only to Concord grapes.

Harvesting. Concord grapes are harvested when their acid level is high. Cold storage at 0°C reduces grape acidity to levels acceptable to consumers. Grapes are harvested mechanically, placed in one-ton bulk boxes equipped with polyethylene liners, and taken to a grading station to measure their soluble solids. Grapes are usually processed within 4 to 6 hours after picking (McLellan and Race 1995).

Washing and inspection of fruit. Grapes are transferred to a stemmer-crusher operation that removes leaves, petioles and stems from the fruit (step 4). The grapes are then put in a rotating perforated drum where they are crushed or broken open. The grapes then enter a tubular heat exchanger where they are heated to 60°C. This process, called hot-break, is designed to extract color and increase juice yield (Pederson 1980a; McLellan and Race

1995). Enzymes (step 4B) and press aids (step 4C) are added. Pressing and screening and filtration are similar to those steps for other products.

Finished product. Juice is flash pasteurized at 79.4 to 85°C for 1 minute, then cooled to 0°C (Pederson 1980a; McLellan and Race 1995). The cooled grape juice is stored in refrigerated tanks for up to one year. During storage some of the natural potassium bitartrate precipitates out as argol, a waste product. Before juice is further processed additional clarification is performed (step 6). The clarified juice is hot filled at a minimum temperature of 82.2°C. Either evaporation (57.2 to 71°C) or a combination of reverse osmosis and evaporation (Pederson 1980a; Downes 1995) can concentrate grape juice.

Imports. Close to one-third of the grape juice consumed is imported (table 1) (*The Almanac of the Canning, Freezing, Preserving Industries* 1996). The United States imports grape juice from North and South America, the Middle East, and elsewhere.

F. CHERRY JUICE

Varieties. Cherry juice can be made from sweet or sour cherries.

Harvesting and inspection of fruit. Cherry juice is made from high quality cherries -- not culls, which usually possess off-flavors. They can be harvested mechanically. Harvested cherries are usually soaked for less than 12 hours in cold (10°C) water (Tressler et al 1980).

Processing and finished product. Cherries are processed in one of three ways: hot pressing, cold pressing, and cold pressing thawed fruit. In hot pressing, cherries are heated to 65.5°C and pressed (step 4 and 5) before being cooled and screened. After the juice is chilled to 10°C, it is allowed to settle overnight and is clarified (step 6). In cold pressing, washed cherries are extracted (step 4) and pressed (step 5). The juice is then heated to 87.7 to 93.3°C and cooled. Pectinase is added and allowed to act for about 3 hours in order to reduce viscosity and clarify the juice. Following this step, the juice is heated to 82.2°C, cooled and filtered. With cold pressing, thawed cherries are crushed and pitted, then frozen. Before pressing, cherries are thawed to about 4.5-10°C. This juice is treated like cold pressed juice. Sugar is normally added to cherry juice to bring it up to 17° Brix. If sweet cherries are used for juice, sour cherry juice will be mixed with it to create proper flavor. Hot and cold pressed juices are usually mixed together to obtain proper color and flavor. Because of its strong flavor, cherry juice is usually blended or mixed with other juices. Cherry juice can be pasteurized to as low as 73.8°C, if air is eliminated in the headspace (Tressler, Charley, and Luh 1980).

G. BERRY AND STONE FRUIT JUICE

Varieties. These fruits include prunes, plums, apricots, strawberries, blackberries, raspberries, cranberries, pears, and similar fruits (Downes 1995).

Harvesting and inspection of fruit. Hand picked fruit is normally of high quality; mechanically picked fruit need not be. Both are used to make juice. After the fruit is picked, debris, mold, and rot are removed before the fruit is washed.

Processing and finished product. Pears and similar fruit need to be pressed at high pressure; berries probably need enzymes and pressing aids as well. These fruits are all processed with their skin on. Different milling and pressing processes (steps 4 and 5) are used for the different fruits. Various clarification and filtration may also be needed, depending on the product (step 6). Some of the berry juices may need de-aeration (step 7). Almost all of these juices can be flash pasteurized at 79.4°C or above for 30 seconds to eliminate microorganisms and oxidative enzymes (Tressler, Charley, and Luh 1980). Either evaporation (57.2 to 71°C) or a combination of reverse osmosis and evaporation (Pederson 1980a; Downes 1995) can concentrate these juices.

Imports. In 1995, the United States imported close to 90 million liters of pear and berry juice (*The Almanac of the Canning, Freezing, Preserving Industries* 1996). We do not have separate estimates of the consumption of those juices; it is likely that imports make up a relatively large share -- perhaps one-third -- of total consumption.

H. PINEAPPLE JUICE

Varieties. The pineapple is a member of the Bromeliaeceae family. It is grown in the tropics, mainly in Hawaii, Thailand, Indonesia, Malaysia and Brazil (Hooper 1995; Inderkum 1994; Mehrlich and Felton 1980).

Processing of fruit. Pineapple juice tends to be a by-product of the pineapple canning industry. The juice is obtained from whole fruits, canning industry fruit, and skin residues (Inderkum 1994; Hooper 1995). The fruit residues are crushed by rollers and the mash is extracted and pressed (steps 4 and 5). The juice from fruit residues is combined with pre-extraction juice before being filtered and pasteurized. The juice is concentrated to 60 or 70° Brix and packed either aseptically or frozen. Reconstituted juice is pasteurized, chilled, packaged, and shipped (step 12).

Imports. Approximately 90 percent of the pineapple juice consumed in the United States is imported (see table 1). Of the imported juice, about 75 percent is concentrate (*The Almanac of the Canning, Freezing, Preserving Industries* 1996). The imported juice comes from the major producing countries, such as Brazil, Indonesia, Malaysia, and Thailand.

I. TOMATO JUICE

Varieties. Many different varieties of tomatoes are used commercially for tomato juice.

Harvesting. Tomatoes are mechanically harvested before they are well colored and ripened; otherwise, harvesting will cause extensive damage to the raw fruit (Leonard 1980).

Washing and inspection of fruit. Tomatoes are sorted in the field to eliminate tomatoes with insect damage, mold, off-color, rot, sunburn, and other flaws. They are then taken to a cannery where they are washed several times. The final wash normally contains at least 5 ppm chlorine. Tomato juice can be extracted using methods in step 4, or by slicing (skin on), pressing (as per step 5), and filtering (step 6). After extraction, heating the juice to 104.4°C for 15 seconds inactivates the natural enzymes pectinesterase and polygalacturonase (Leonard 1980). Tomato juice also requires de-aeration (step 7).

Finished product. Tomato juice is homogenized after de-aeration to prevent settling and separation. Salt is added from 0.5 to 1.25 percent by weight to improve juice flavor. Tomato juice contains less acid than many other juices, so more severe heat processing is necessary. Tomato juice must be processed to temperatures that eliminate *Bacillus coagulans* -- 118.3°C for 1.5 minutes, 121.1°C for 42.0 seconds (steps 8 and 10) (Leonard 1980). Tomato juice is not usually concentrated by heat, because heat concentration affects taste (Francis and Harmer 1988).

Imports. Very little tomato juice is imported (*The Almanac of the Canning, Freezing, Preserving Industries* 1996).

J. OTHER VEGETABLE JUICES

Types. Vegetable juice may be obtained from leaf or stem vegetables such as beet leaves, cabbage, celery, lettuce, rhubarb, and others. Juice may also be obtained from root vegetables -- beets, carrots, onions, parsnips, sweet potatoes -- and seed bearing plants, including cucumbers, pepper, and others.

Harvesting. Vegetables can be harvested by hand or by machine. Vegetables are normally harvested before maturity in order to reduce mechanical damage during handling and processing.

Washing and inspection of fruit. Vegetables are sorted and trimmed to eliminate those with insect damage, mold, off-color, rot, sunburn, and other flaws. After being sorted, the vegetables are washed in water that contains from 10 to 200 ppm chlorine (Powrie and Skura 1991). Vegetable juices can be extracted using methods in step 4, or slicing (skin on), pressing (step 5), and filtering (step 6). If a vegetable was not heated before juice extraction, it is necessary to heat-treat the extracted juice to inactivate the natural enzymes. Although the enzymes are inactivated in tomato juice by heating juice to 104.4°C for 15 seconds, other vegetables may be heated to different temperatures. Some vegetable juices may also require de-aeration.

Finished product. Many vegetable juices are non-acidic and therefore require severe heat processing to inactivate enzymes and microorganisms. Vegetable juices may be processed to temperatures of 115.5 to 121.1°C (steps 8 and 10). If acid is added to the vegetable juice, then less heat treatment is necessary (Pederson 1980b). Vegetable juices are not normally concentrated by heat, because heat concentration affects taste (Francis and Harmer 1988).

Imports. Imports are negligible, as is total consumption of non-tomato-based vegetable juices.

K. PACKAGING

Glass bottles are the traditional containers used for fruit and vegetable juices (Paine and Paine 1992 is the reference for this entire section). Glass is inert, easy to clean, durable and rigid, and impermeable to odors, vapors and liquids. Juices can either be hot-filled or pasteurized in the bottle.

Polyethylene (PET) and polyvinyl chloride (PVC) bottles can also be used for juices, but these bottles become distorted at temperatures above 65-70°C. Polyethylene bottles covered with polyvinylidene chloride have reduced gas permeability. Because they rely on internal pressure to provide rigidity, they are best suited for carbonated juices. Orange juice has been packed in clear oriented polypropylene bottles because this material provides good oxygen and moisture barriers.

High-acid juices are packed in lacquered and coated cans. Cans are usually hot filled but they may also be cold filled. Cold filled juice is pasteurized and then placed in the can; this type of canned juice requires refrigeration.

Frozen orange juice concentrate is packed in composite paperboard canisters. Bulk frozen orange juice is packed into 200 liter polyethylene drums or polyethylene lined drums. Pasteurized fruit juices can be packed in polyethylene-coated cartons. These products must be stored in refrigerators. Pasteurized juice can be stored long term under frozen conditions. All juice containers, except those aseptically packaged, benefit from cool storage.

IV. Potential Introduction of Hazards into Juice Products: What Can Go Wrong

In the previous section we described common production methods for fruit and vegetable juices. In this section we discuss possible hazards and theoretical points in the production process where hazards might enter.

A. MOST COMMON HAZARDS

Three types of hazards may affect juice products: microbiological, chemical, and physical. Of these, microbiological hazards are the most severe.

The primary microbial hazards that have been found in fruit juices are *Escherichia coli* O157:H7, *Cryptosporidium parvum*, *Bacillus cereus*, and *Salmonella* spp. Table 4 contains information on those outbreaks and recalls for which there have been confirmed cases with juice as the vehicle. The 1996 outbreaks were associated with *E. coli* O157:H7 and *C. parvum*. Past outbreaks and isolated cases have involved *Vibrio cholerae* O1 and *Clostridium botulinum*.

The microbial hazards identified from the history of pathogen-related outbreaks from juice products do not exhaust the potential microbial hazards; emerging pathogens may be more serious than any currently identified hazards. The outbreaks associated with *E. coli* O157:H7 and *C. parvum* involved pathogens that were unknown a generation ago.

B. HAZARD ENTRY POINTS

The outline below shows areas where hazards may enter juice products. This information may be useful in assessing the likelihood of hazard entry for purposes of (for example) a Hazard Analysis Critical and Control Point (HACCP) hazard assessment.

Contamination can occur within any of the 12 steps associated with juice production described above and in table 3. Some of the theoretically possible modes of entry for hazards include:

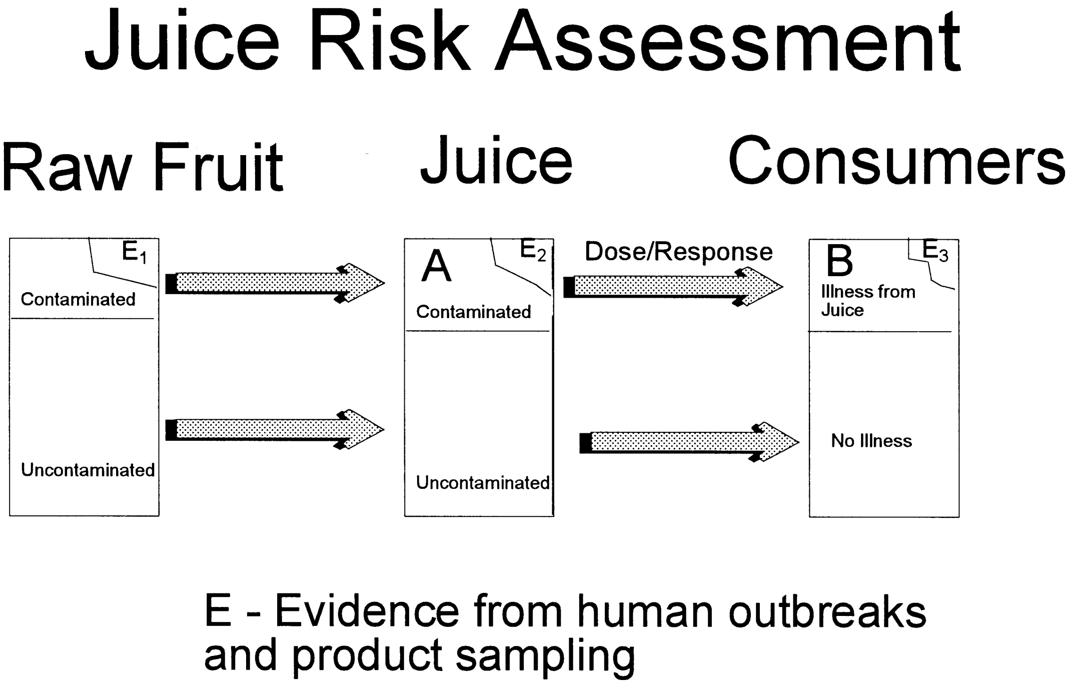
1. Raw Product: (steps 1 and 2)
    a. Contamination by airborne pathogens (from nearby farms, for example)
    b. Contamination by fertilizer
    c. Contamination by wild or domestic animal feces (especially drop fruit)
    d. Contamination by non-potable water used to apply pesticides
    e. Contamination during shipping
    f. Human contamination

  - g. Pesticides or herbicides during farm production
  - f. Raw Product -- metals, stones
- 2. Contamination during processing (steps 3 through 12)
  - a. Contaminated by unsanitary wash water
  - b. Contamination during extraction, pressing or clarification
  - c. Contamination following heat treatment or during bottling
  - d. Contamination by humans following heat treatment of juice
  - e. Processing -- chemical sanitizers
  - g. Processing -- filtration screens, glass (from breaking bottles, plastic)
- 3. Post-Processing Contamination
  - a. Contamination during storage and shipping

Adequate heat treatment (pasteurization or further heat treatment) will inactivate heat-sensitive pathogens resulting from contamination occurring in steps 1(a) through (f) or 2 (a) through 2 (b). Non-heat methods, such as pulsed light or filtration, may also inactivate these pathogens.

V. The Level of Contamination and the Probability of Illness: Evidence that Something Has Gone Wrong

The probability of illness resulting from consumption of contaminated juice products may be divided into two underlying probabilities: 1) the probability that the juice becomes contaminated (at some level), and 2) the conditional probability that, given that the juice is contaminated, drinking it makes humans ill. The probability of illness from drinking juice contaminated with microbial pathogens is positively related to the degree of contamination as measured by the number of organisms (or dose) consumed. As with most hazards associated with juices, however, the evidence needed to estimate these two probabilities -- the probability that juice is contaminated and the probability of illness from consuming contaminated juice -- is either fragmented or missing. The diagram below illustrates the relationship between the two probabilities and the role of the supporting data that are generally available to estimate these probabilities.


Juice Risk Assessment

E - Evidence from human outbreaks and product sampling

As the diagram illustrates, the evidence on product contamination and human illness (areas E_1, E_2, and E_3) from microbiological hazards are small, unknown proportions of total contamination and illness. Contamination may start with the raw fruit or vegetable and be carried through processing into juice. Contamination may occur during processing. Product sampling provides the most telling evidence that juice is contaminated. If, however, the underlying rates of contamination are low and contamination is sporadic, it may be impossible to sample enough product to estimate rates of contamination with any statistical precision. One sample snapshot will not provide an accurate description of the average amount of contaminated raw product or the resulting amount of contaminated juice.

Once juice is contaminated, some people will likely become ill. If we knew the amount of contaminated juice (area A), the level of contamination (organisms per unit of volume), and the dose-response relationship, we could predict the number of illnesses (area B) and deaths likely to result from consuming the contaminated juice. Because we do not know the amount of contaminated juice, the level of contamination, or the dose-response function, we cannot estimate the total amount of illness by combining the three variables. Instead, we must infer the total amount of illness from the data on reported outbreaks -- a small and unknown fraction of total illnesses.

In order to use the epidemiological data from an outbreak to estimate a dose-response function, we would need to determine the total population exposed to contaminated juice, verify that juice was the vehicle, estimate the dose consumed, and classify the symptoms and complications. In order to estimate the full human dose-response relationship for a particular pathogen-product combination (such as *E. coli* O157: H7 in apple juice), we would need a large, representative sample of outbreak data, with estimated doses consumed and the percent of consumers who became ill at each dose level.

Because we lacked an evidence-based dose-response model, we looked at the evidence linking the microbial contamination of juices to the epidemiological evidence on the microbial illnesses associated with juices.

A. THE LEVEL OF CONTAMINATION

1. Discussion

Contamination may occur during growth, harvesting, processing, or post-processing of fruits and vegetables. The level of exposure (pathogen count or quantity) is a function of the initial amount of the hazard introduced into the product and subsequent increase or decrease of the hazard (if any) before consumption. For microbial hazards, the dose in the final product will be a function of (1) the initial microbial load and (2) the multiplication or inactivation of the pathogens during processing, storage and distribution.

The probability that the raw product is contaminated with a microbial pathogen depends on whether domestic or wild animals are in or near the growing area, the source of water, the use of drop apples (or the equivalent for other fruit), the type of fertilizer used (particularly manure), and the frequency and method of washing the raw fruit. Animal feces cause contamination either directly by contaminating drop apples or indirectly by contaminating workers, water, or possibly air. The use of manure also increases the probability of contamination. Well water is more likely to be contaminated than water from a municipality or other qualified provider. Washing the fruit tends to reduce contamination, unless the water itself is contaminated.

Once the juice has been contaminated, the pathogens may either multiply or become inactivated. For bacterial and fungal pathogens, the number of organisms will increase at different rates depending on the pathogen, the package, the storage temperature, and the specific characteristics of the juice, particularly the acidity and water activity. With low temperatures, low water activity (low a_w), or acidic conditions (low pH), the pathogens may not survive or may fail to multiply. Recent studies indicate, however, that the specific characteristics of juices cannot be expected to completely inactivate all microbial pathogens.

Several organisms, including an *E. coli* O157: H7 strain (ATCC 43895) can survive exposure to extremely acidic ($pH < 3$) environments (Leyer, Eang, and Johnson 1995; Benjamin and Datta 1995). Most juices, including apple ($pH = 3.4 - 4.0$), orange ($pH = 3.6 - 4.3$), grapefruit ($pH = 3.0$), prune ($pH = 3.7$), tomato ($pH = 4.1 - 4.2$), and pineapple ($pH = 3.5$), are not acidic enough ($pH \geq 3$) to guarantee pathogen inactivation (U. S. Food and Drug Administration 1997a). Sugar reduces water activity (a_w); the reduced water activity can lead to pathogen cell shrinkage and death (Branen and Davidson 1983). The sugar concentrations in juices, however, are probably too low to ensure safety. Fruit juices have water activity levels of about 0.97; an activity level of 0.80 would be necessary for microbial safety (Peterson and Johnson 1978; Thorner and Herzberg 1970). Freezing will prevent multiplication, but will not kill bacterial pathogens (Council for Agricultural Science and Technology [CAST] 1994). Parasites (e.g., *C. parvum*) and human viruses (e.g., Norwalk virus) will not multiply in juice, but will not be inactivated..

Apple and other juices produced by pressing or other methods that introduce skin into the product are likely to contain contaminants before processing, because sterile field conditions are highly unlikely. The outbreak literature contains examples of contamination from nearby cattle, from deer in the orchard, and possibly from sheep (see citations in table 4). Few farmers report that livestock are allowed to graze in the orchards (U. S. Apple Association 1997a). Orchards are, however, often located near livestock or wildlife with the potential for microbial contamination. *E. coli* O157: H7 has been cultured from the feces of deer, sheep, pigs, goats, dogs, birds, flies, and a horse (Randall, Wray, and Mclaren 1997; Keene et al. 1996; Rice, Hancock, and Besser 1995).

Farmers can take steps to reduce the likelihood of contamination from these sources, but it is impossible to eliminate microbial pathogens from all raw fruits and vegetables. The microbial pathogens that have been found in juice are widespread in animal feces and are therefore likely to be present in soil, water, and air.

2. Evidence

The ideal way to gather evidence on the morbidity and mortality associated with juices would be to carry out a prospective statistical survey that linked evidence on the microbial contamination of juices with evidence on subsequent human illness, but no one has done such a survey. The best current evidence that some juice is contaminated came from retrospective outbreak investigations, which demonstrated an association between illness outbreaks and juice consumption. In four of the outbreaks listed in table 4, investigators were able to isolate the pathogen from the product itself. *Salmonella typhimurium* was isolated from two bottles of apple cider taken from homes of victims of the 1975 outbreak. In the 1993 *C. parvum* outbreak from fresh-pressed apple cider, oocysts were detected in the leftover cider and on swabs from the surface of the cider press. In the outbreak of salmonellosis from orange juice in 1995, the Centers for Disease Control and Prevention (CDC) investigators cultured *Salmonella* spp. from 10 of 12 juice containers and from all 4 juice lots represented. An FDA laboratory found *E. coli* O157:H7 in one sample of apple juice from the 1996 outbreak and recall associated with unpasteurized apple juice.

Recalls provide even more direct evidence of juice contamination. In the 1994 orange juice recall listed in table 4, 4 of 6 samples analyzed for *B. cereus* tested positive. For the 1992 Orange Julius recall, 2 of 13 samples tested positive for *Salmonella* spp.

We can also call upon circumstantial evidence suggesting that at least some juice products will be contaminated. We know which conditions and practices are likely to cause microbial contamination and we know that some of the conditions and practices are widespread. For example, according to the industry survey, 55 percent of cider producers use drop apples, 97 percent do not pasteurize their cider, and 8 percent do not wash apples before pressing (U. S. Apple Association 1997a). As long as these practices continue, some apple cider will likely be contaminated with microbial pathogens.

The prevalence of practices that can lead to microbial contamination, when combined with outbreak and recall investigations that have found contaminated juices, establishes the plausibility of juices as the vehicles for illnesses. Because we do not have evidence on the level and types of contamination, the importance of the health hazard cannot be measured by the level of contamination of fruit and vegetable juices. Instead, we measure the health hazard as the number of illnesses associated with the consumption of juices.

B. PROBABILITY OF ILLNESS

1. Discussion

Once the contaminated product finds its way to consumers, the dose of the microbial pathogen is only one component affecting the probability of illness. The age and immune status of the exposed population, and individual characteristics -- such as the acidity of the stomach -- affect both the probability and the severity of illness at a given dose. Children accounted for all of the known severe cases from one recent *E. coli* O157:H7 outbreak associated with unpasteurized apple juice.

We did not have sufficient information on the age and immune status of consumers of the various juice products to incorporate those variables into the estimates of the number of illnesses causes by juices. The numbers presented below, then, do not distinguish between consumers of different age or immune status.

2. Evidence

Table 4 contains all the of evidence that we have accumulated on microbial illnesses resulting from juice consumption. The table lists the outbreaks of illness reported to the Centers for Disease Control and Prevention (CDC), FDA recalls, and state health agencies' investigations associated with microbial pathogens in juices and juice drinks. In order to avoid double-counting, when an event appeared in more than one data base, we listed the CDC outbreak data only; if the event did not appear in the CDC records but was in both FDA recall data and state health records, we listed it under FDA recalls. The table contains 21 events: 13 outbreaks, 3 recalls, and 5 incidents reported by state health departments. The products involved were apple juice or cider (8 events), orange juice (5 events), tomato juice (4 events) coconut milk (1 event), carrot juice (1 event), watermelon juice (1 event), and flavored drinks (1 event). The pathogens were *E. coli* O157: H7 (5 events), *Salmonella* spp. (5 events), *C. parvum* (3 events), *B. cereus* (1 event), *Vibrio cholerae* O1 (1 event), *Clostridium botulinum* (5 events), and unknown (1 event).

According to Centers for Disease Control and Prevention outbreak data, state outbreak data, and FDA recall records, juices accounted for 447 confirmed illnesses from 1993 through 1996 (see table 4). The breakdown by pathogen was 62 *Salmonella* spp., 86 *E. coli* O157: H7, 85 *B. cereus*, 191 *C. parvum*, and 23 cases caused by an unknown pathogen. The products associated with illnesses were apple juice or cider (277 cases) and orange juice (170 cases).

No estimates of the annual number of all juice-related microbial illnesses exist. Most observers agree that the total number of cases exceeds the reported cases, but no consensus exists on the magnitude of the difference. The uncertainty can be seen in the estimates of the total number of foodborne illnesses caused by the four pathogens that have been associated with juices since 1993.

The most information on incidence of foodborne microbial illnesses is for *Salmonella*. The National *Salmonella* Surveillance System of the Centers for Disease Control and Prevention collects reports of *Salmonella* isolates from throughout the U. S.; the annual number of isolates averages about 40,000 (CDC 1996c). The CDC also includes *Salmonella* as one of the pathogens followed by its sentinel sites survey program. The CDC's 5 sentinel sites (representing 5 percent of the U. S. population) reported 2,142 laboratory-confirmed cases of foodborne illness attributable to *Salmonella* spp. in 1996 (USDA 1997), implying that 42,840 (2,142 × 20) total laboratory-confirmed cases could have occurred in 1996. The extrapolation from the sentinel sites comes close to the 40,000 average annual laboratory-confirmed cases in the CDC national *Salmonella* surveillance project.

The total number of illnesses caused by *Salmonella* exceeds the number of laboratory-confirmed cases, but by an uncertain amount. In some early surveys based on investigations of outbreaks, epidemiologists found that unreported cases might be about 100 (or more) times reported cases (Aserkoff, Schroaeder, and Brachman 1970). That estimate has often been used as an upper-bound multiplier for converting reported cases of salmonellosis into estimated total cases (Helmick et al. 1994). More recent estimates of total cases derived from reported cases usually include both lower-bound and upper-bound multipliers. Cohen and Tauxe (1986) suggested that between one and 10 percent of cases of salmonellosis were reported, for a multiplier range of 10 to 100. Chalker and Blaser (1988) found the median ratio of estimated total cases to reported cases in 8 outbreaks to be close to 20. In another section of the same paper, Chalker and Blaser used the carriage rate for *Salmonella* to estimate the annual number of infections. The carriage rate of 0.15 percent combined with the infection duration of about 5 weeks (0.096 years) implied an estimated annual infection rate of approximately 1.5 percent (0.15 percent ÷ 0.096 years). With an infection rate of 1.5 percent, we would expect about 4 million infections per year (0.015 × 260 million).

Chalker and Blaser concluded that the number of laboratory-confirmed cases of salmonellosis represented 1 to 5 percent of all cases, which remains the most widely-cited range for the rate of reported cases. Multiplying the 40,000 annual cases in the CDC *Salmonella* surveillance by 20 to 100 generates an estimated 800,000 to 4,000,000 of annual illnesses caused by *Salmonella*, a range cited by Helmick et al. (1994), Buzby and Roberts (1996), and in much of the literature on foodborne diseases.

The most widely cited point estimates of the annual number of illnesses are Bennett et al. (1987), who estimated the annual number of foodborne *Salmonella* cases to be 1,920,000, and Todd (1989), who put the number at 2,960,000. Bennett et al. relied on the judgment of experts from CDC who reviewed the evidence from outbreak investigations and the surveillance reports to come up with an estimated 2,000,000 total cases, with 96 percent foodborne (0.96 × 2,000,000 = 1,920,000). Todd estimated the number of cases in several ways, but selected the median estimate as the most likely. His median was the mid-point between Bennett et al.'s 1,920,000 cases and the standard upper bound of 4,000,000 cases. Because CAST (1994) included both point estimates, we used them to generate two different upper bounds on the number of *Salmonella* cases associated with juices.

The relatively recent emergence of *E. coli* O157:H7 as a major foodborne pathogen meant that we had fewer estimates of its incidence. The Centers for Disease Control and Prevention's 5 sentinel sites reported 384 laboratory-confirmed cases of foodborne illness attributable to *E. coli* O157:H7 in 1996 (USDA 1997). The sentinel sites cover about 5 percent of the U. S. population, which implies that 7,680 (384 × 20) total laboratory-confirmed cases could have occurred in 1996 -- if the sentinel sites are representative of the entire population. Because many cases are either not reported or not confirmed, the true number may be higher. Boyce, Swerdlow, and Griffin (1995) applied the infection rate from a prospective population study conducted in Washington state -- 8 per 100,000 people -- to the U. S. population to get an estimated 21,000 annual infections. According to the Council for Agricultural Science and Technology (CAST) 1994 report, other studies found infection rates as low as 3 per 100,000. If the two estimated infection rates represent lower and upper bounds, then 7,668 to 20,448 cases of *E. coli* O157: H7 illness occur per year (0.00003 × 260,000,000 to 0.00008 × 260,000,000).

Todd (1989) included three estimates of the annual number of *E. coli* O157: H7 illnesses. He generated two of the estimates by inflating the annual average number of outbreak cases for the years 1978-1982 with different multipliers; he generated the third estimate by extrapolating from Canadian data. Todd chose the median of the three estimates, 25,000, as the best point estimate of the annual number of illnesses attributable to *E. coli* O157:H7. His chosen estimate of 25,000 equaled the average annual outbreak cases in 1978-1982 --30 -- multiplied by the implicit multiplier -- 826 -- linking *Salmonella* cases as estimated in Bennett et al. (1987) to reported outbreak cases. Todd's estimate for the incidence of foodborne *E. coli* O157:H7 assumed that the degree of under-reporting for *E. coli* O157:H7 was identical to the degree of under-reporting implicit in Bennett et al.'s estimated incidence of foodborne *Salmonella*. CAST (1994) reproduced Todd's estimate as the best point estimate of the annual number of cases of illness caused by *E. coli* O157:H7.

C. parvum is also a newly recognized foodborne microbial hazard. Although human infection with *C. parvum* was first confirmed in 1973, the first confirmed foodborne outbreak occurred in 1993. The distinctive symptoms of cryptosporidiosis -- long-lasting watery diarrhea -- make it likely that outbreaks will be noticed. The most important outbreaks associated with this pathogen have come about as a result of contaminated water. In an outbreak associated with municipal drinking water, over 400,000 people may have become ill (Mac Kenzie et al. 1994). According to a recent study of 199 sites in 23 states, *C. parvum* was present in 11 percent of all groundwater (Hancock, Rose, and Callahan 1997). The groundwater tested and found positive came from vertical wells (5 percent positive), springs (20 percent positive), infiltration galleries (50 percent positive), and horizontal wells (45 percent positive).

If the contaminated water comes into contact (directly, or indirectly through an animal carrier) with the fruit or juice and is not pasteurized, illness will likely occur. The cider-related outbreaks caused by *C. parvum* demonstrate that this event has occurred (see table 4). The CDC attributed the cider-related 1996 outbreak to the use of contaminated well-water to rinse the apples used to make cider.

C. parvum has emerged too recently for there to be estimates of its foodborne incidence. Moreover, producing estimates of the incidence of foodborne cryptosporidiosis is complicated by the difficulty of distinguishing foodborne from other sources of *C. parvum*. For example, the 1993 waterborne outbreak may have included some cases associated with juice drinks made with contaminated water (see table 4). Several products made with municipal water were recalled, but the far greater direct contact with contaminated water made it impossible to determine how many illnesses were associated with juice drinks. Person-to-person transmission of *C. parvum* may also make estimating its foodborne incidence difficult. In the 1993 outbreak associated with apple cider contaminated with *C. parvum*, the 160 primary cases caused by cider consumption led to 53 secondary cases caused by person-to-person contact (Millard et al. 1994).

The symptoms of *B. cereus* food poisoning are short-lived (see below). For this reason, the illness may be the most under-reported of those that we have identified as juice-related microbial pathogens. The potential for a large degree of underreporting leads to more uncertainty in the estimated *B. cereus* incidence than for any other of the pathogens we associated with juices. The experts in Bennett et al. (1987) put the number of illnesses at 5,000 per year. Todd (1989) used two *Salmonella* multipliers -- 350 (his own) and 826 (from Bennett at al. 1987) -- to inflate the 142 annual average *B. cereus* cases from the 1978-1982 CDC outbreak reports; the resulting estimates equaled 49,700 (350 × 142) and 117,416 (826 × 142). Todd's best point estimate, 84,000 annual cases, was approximately midway between the two estimates generated by the multipliers. The CAST (1994) report included both 5,000 and 84,000 as estimated annual incidences of *B. cereus* food poisoning.

3. Estimates of the Number of Illness from Consuming Juices

In order to estimate the number of illness from the consumption of juices, we used estimates of the frequency of reported juice-related illnesses in the years 1993 to 1996. We assumed that estimated frequencies of illnesses in recent years constituted the best estimates of the current frequency of illnesses. To generate the estimated frequencies, we found it necessary to make several assumptions that were not based on evidence. For that reason, the estimated numbers of illnesses must be regarded as highly uncertain. As more data and better models become available, we expect these estimates to change.

As table 4 shows, 447 confirmed illnesses of widely varying severities -- an annual average of 112 -- can be associated with juices in 1993-1996. The 112 illnesses included annual averages of 16 *Salmonella*, 22 *E. coli* O157: H7, 48 *C. parvum*, 21 *B. cereus*, and 6 cases with unknown pathogens per year. We used these averages as our lower-bound estimated annual number of illnesses associated with juices. Generating upper-bound estimates proved more difficult. We believe 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. Estimating the total number of illnesses associated with juices therefore required going well beyond the data. We estimated the total number of juice-related illnesses by multiplying the average number of 1993-1996 reported cases by factors that account for under-reporting. Because the under-reporting probably differs by pathogen, the multipliers differed for the four pathogens.

The multipliers (20 to 100) cited above for the annual number of illnesses caused by *Salmonella* apply to the annual number of laboratory-confirmed cases recorded by the CDC surveillance system. Because the confirmed cases of juice-related illnesses in table 4 came from outbreak and recall data, we could not use multipliers based on the surveillance numbers. Instead, we chose multipliers appropriate for outbreak cases. The state data and recall data (see table 4) came from events like CDC outbreaks -- not from passive surveillance.

The decision to use multipliers appropriate to outbreaks proved straightforward, but the selection of specific multipliers posed problems. Neither Todd (1989) nor Bennett et al. (1987) used explicit multipliers for *Salmonella*. Bennett et al. made no explicit connection between outbreak cases and total cases, but it is possible to compute an implicit multiplier by dividing their estimated total cases by outbreak cases of *Salmonella*. Todd used Bennett et al.'s implicit *Salmonella* multiplier for *E. coli* O157:H7 and as part of the estimates for *B. cereus* and *Salmonella* itself. The multipliers used by Todd, however, applied to outbreak cases from 1978-82, and -- if applied to the more recent outbreak data -- would not generate the same estimated numbers of illnesses. For that reason, we computed new multipliers based on more recent outbreak data.

CAST (1994) described the estimates of foodborne illnesses from Bennett et al. (1987) and Todd (1989) as "not at the high or low ends of the ranges and generally are considered by CAST tasks force members to be estimates based on defensible assumptions." Because both Todd and Bennett were members of the CAST task force, we assumed that they both continued to accept their earlier estimates of incidence. The

CAST report contained five estimates of foodborne illnesses caused by the pathogens we identified as the hazards associated with juices -- two estimates each for *Salmonella* and *B. cereus*, one estimate for *E. coli* O157:H7. The report contained no estimates of the number of illnesses caused by *C. parvum*, which was only recognized as a foodborne hazard in 1993. The most recent CDC foodborne outbreak data in the CAST report (based on Bean et al. 1990) covered the years 1983-1987. We therefore computed implicit multipliers based, when possible, on the ratios of Todd's or Bennett et al.'s estimated cases to average annual outbreak cases for 1983-1987. The implicit multipliers for each pathogen equaled the estimated annual number of total foodborne cases divided by the annual number of outbreak cases in 1983-1987. The main disadvantage of this procedure was that the base years for reported cases were a decade old. Another disadvantage, the absence of estimated cases of foodborne *C. parvum*, forced us to use a default multiplier for that pathogen.

After computing the multipliers from outbreak data and estimated cases of all foodborne illness, we used them to generate upper-bound estimates of the annual amount of juice-borne illness in 1993-1996. We assumed that the relationship between confirmed juice-related outbreak cases and total estimated cases of juice-related microbial illnesses in the years 1993-1996 was identical to the relationship between confirmed foodborne outbreak cases in 1983-1987 and total estimated cases of foodborne microbial illnesses. The assumption, although unlikely to be precisely correct, led to no obvious bias. We then generated upper-bound estimates of the number of cases associated with each of the four pathogens by multiplying the number of reported juice-borne cases by the implicit multipliers. Table 5 shows the results.

The annual average number of outbreak cases caused by *Salmonella* spp. in 1983-1987 was 6,249. With the estimate of total cases based on Bennett et al. (1987), the ratio of total to confirmed outbreak cases of salmonellosis equaled 307 (1,920,000 ÷ 6,249). The implicit multiplier of 307 generated an estimate of 4,900 (16 × 307) annual cases of juice-borne salmonellosis (table 5, column 3). In the estimate based on Todd (1989) the ratio of total to confirmed outbreak cases of salmonellosis equaled 474 (2,960,000 ÷ 6,249). The implicit multiplier of 474 generated an estimate of 7,600 (16 × 474) annual cases of juice-borne salmonellosis (table 5, column 4).

We estimated the number of juice-related illnesses attributable to the other pathogens with the same method used for *Salmonella*. The average annual number of outbreak cases caused by *E. coli* O157: H7 in 1983-1987 was 128. Because Bennett et al. (1987) made no estimates of the illnesses attributable to *E. coli* O157: H7, we used 100 as a default multiplier --100 remains the standard multiplier in the literature on under-reporting of microbial illness. The estimated number of *E. coli* O157: H7 illnesses attributable to juices was 2,200 (22 × 100) (table 5, column 3). In the estimate based on Todd (1989), the ratio of total to confirmed outbreak cases of *E. coli* O157: H7 equaled 195 (25,000 ÷ 128). That multiplier led to an estimated 4,300 (22 × 195) annual cases of illness attributable to juices (table 5, column 4).

Because we lacked estimates from Bennett et al. (1987) or Todd (1989) of the annual number of illnesses caused by foodborne *C. parvum*, we again used 100 as the default multiplier linking reported outbreak cases to total juice-related cases. The 48 average annual cases of cryptosporidiosis generated an annual juice-related illnesses estimate of 4,800 (table 5, columns 3 and 4).

B. cereus displayed the largest difference in estimated cases. Outbreaks of *B. cereus* illness led to an average of 52 cases per year in 1993-1996. Bennett et al. (1987) estimated the annual number of cases to be 5,000. With a ratio of total to confirmed outbreak cases of 96 (5,000 ÷ 52), the estimated number of juice-related cases would be 2,000 (21 × 96) (table 5, column 3). In Todd (1989), the estimated *B. cereus* illnesses equaled 84,000. The ratio of this estimated total to confirmed outbreak cases of *B. cereus* was 1,615 (84,000 ÷ 52). This implicit multiplier generated an estimate of 33,900 (21 × 1,615) for annual *B. cereus* cases associated with juices (table 5, column 4).

The large difference between the two estimates of *B. cereus* illnesses came from the extremely large difference in the two multipliers used to link reported and actual cases. The large range of implicit multipliers for *B. cereus* reflects the large uncertainty associated with that illness; the uncertainty exists because the short-lived symptoms cause *B. cereus* illness to seldom be reported.

We applied the default multiplier of 100 to the unknown pathogen, for a total of 600 cases. The sum of the *B. cereus* cases and cases associated with the unknown pathogen represent the total cases of illnesses associated with heat-treated juices. With the *B. cereus* multiplier based on Bennett et al., the total annual estimated illnesses associated with microbial pathogens in heat-treated juices would be 2,600 (2,000 + 600). With the multiplier based on Todd, the total would be 34,500 (33,900 + 600).

The multipliers we used to estimate total cases based on reported cases embodied much uncertainty. Moreover, multipliers derived from estimates of all foodborne illnesses may not be applicable to the sub-category of juice-borne illnesses. It is also likely that for a sub-category such as fruit and vegetable juices, the multipliers vary greatly from year to year. We regard these multipliers and the resulting estimated numbers of illness not as definitive but as a first attempt to link reported and unreported cases of juice-related illness. We look forward to improved multipliers and estimates of unreported cases from the results to be generated by the CDC sentinel site project.

VI. Human Health Effects

The descriptions of illnesses presented below apply to all cases of the illnesses, not to juice-related cases alone. Although the symptoms might differ for juice-related cases, we assume that the differences are not systematic. The evidence regarding frequencies of illnesses of different severity is summarized in table 6. The table is not intended to be comprehensive and is not specific to juices; the frequencies and patient outcomes will differ for different doses and serotypes of pathogens. The microbial pathogens that have been associated with outbreaks all lead to gastrointestinal symptoms of varying severity and duration. The outbreak cases listed in table 4 may not have had the same distribution by severity of illness as described in table 6, because reported cases tend to be more severe than unreported cases. Persons suffering from mild gastrointestinal symptoms seldom seek medical care and do not show up in the disease data bases.

The symptoms accompanying *E. coli* O157: H7 illness include diarrhea, bloody stools, abdominal pain, and cramping. In about one-half of all cases, vomiting will occur; something less than one-third of all victims will suffer fever. Mild cases, which are characterized by diarrhea, abdominal pain, and nausea, account for about one-half of the total (CAST 1994). Mild cases last less than four days; victims do not consult physicians (Buzby et al. 1996). In moderate cases, which account for 32 percent of the total, muscle pain and dehydration can occur in addition to the gastrointestinal symptoms. Moderate cases last 4 or more days and involve at least one visit to a physician. Severe cases, which require hospitalization, account for 18 percent of the total. The probability of a severe case of the illness is much greater for the immunocompromised than for the immunocompetent. It is also typically the immunocompromised who develop the long-term and more serious health consequences associated with this pathogen. Those consequences can include hemolytic uremic syndrome (HUS), thrombotic thrombocytopenic purpora (TTP), or death (Griffin 1995). Children and the elderly are at greater risk of developing hemolytic uremic syndrome (CAST 1994). About one-half of fatalities attributed to *E. coli* O157: H7 are caused by hemolytic uremic syndrome; the other half are caused by hemorrhagic colitis. Estimated fatality rates range from 1 to 2.5 percent (Griffin 1995; CAST 1994; Buzby et al. 1996).

Reported outbreak cases provide direct evidence on the human health effects of *E. coli* O157:H7. The 19 *E. coli* O157:H7 outbreaks that occurred between February 1982 and March 1993 resulted in 1,557 confirmed cases of illness. Of those cases, 23 percent required hospitalization and 6 percent developed hemolytic uremic syndrome. 19 people -

- 1.2 percent of the total -- died (Griffin 1995; Boyce, Swerdlow, and Griffin 1995). Because outbreak cases tend to be of greater than average severity, these percentages probably overstate the frequency of severe outcomes for all cases. The percentages of juice-related cases leading to hospitalization and hemolytic uremic syndrome, however, exceeded the percentages for all 19 outbreaks (see table 4).

Symptoms of salmonellosis vary by serotype and by the immune status of the victim. Diarrhea, nausea, vomiting, fever, and headache lasting anywhere from a day to a week characterize a typical case of salmonellosis. A mild case might last two days, whereas a moderate case could last a week or more. Severe cases, which can last up to three weeks, usually require hospitalization. Reactive arthritis and Reiter's syndrome are potential long-term consequences. The estimated distribution of cases between mild, moderate, and severe depends on dose and on the population at risk. At doses that have been associated with past outbreaks, mild cases are estimated to account for about 60 to 70 percent, moderate cases for 20 to 30 percent, and severe cases 5 to 15 percent of all cases (Mauskopf et. al. 1988; Martin et al. 1993). Fatal cases account for less than 0.1 percent of the total (CAST 1994).

Salmonella typhi leads to a severe illness characterized by fever, headache, coughing, nausea, vomiting, diarrhea, dehydration, rash, weakness, and malaise. The illness may last several weeks and usually requires hospitalization. The case fatality rate is 6 percent (CAST 1994)

C. parvum causes watery diarrhea, nausea, vomiting, abdominal pain, and cramping. Cryptosporidiosis lasts from one to several weeks. In a study of the 1993 Greater Milwaukee outbreak, CDC used the following severity classifications: a mild case meant that the patient did not seek health care; a moderate case meant at least one physician visit or emergency room visit but no hospitalization; a severe case required hospitalization. For the Greater Milwaukee outbreak associated with drinking water, the distribution of severity was 90 percent mild, 9 percent moderate, and 1 percent severe (Haddix 1997).

Cryptosporidiosis can also lead to certain chronic health problems, including cholycystitis, hepatitis, and pancreatitis. For some immunocompromised people, such as AIDS victims, cryptosporidiosis can be progressive and possibly fatal.

B. cereus food poisoning has been associated with diarrhea and abdominal cramping. The illness caused by the *B. cereus* diarrhea toxin usually lasts less than one day, and victims seldom seek medical care. The illness caused by the *B. cereus* emetic toxin lasts longer and can lead to vomiting, but has mainly been associated with rice and other starchy foods.

VII. Not Heat-Treatable Hazards

The microbial pathogens do not exhaust the potential human hazards associated with fruit and vegetable juices. The other hazards, mostly not heat-treatable, include various materials that can be inadvertently introduced into the product, such as chemical contaminants and metallic substances. Outbreaks and product recalls (see table 7) provide the main evidence that these hazards may be present in juice and juice drinks. Product recalls have been issued because of the presence of lead, tin, copper, sulfites, sodium hydroxide, unlabeled yellow dye #5, natamycin, salt, milk, glass, and plastic. The presence of pesticides, tin, fluoride, viruses, toxic seed material from guanabana fruit, and the poisonous parts of the elderberry plant have caused outbreaks.

These hazards are diverse in their health consequences (all information on health effects in this section comes from the U. S. Food and Drug Administration's (1997b) Health Hazards Evaluation Board Report). Lead "represents a long-term, chronic hazard of negative consequences on neurological-behavioral and cognitive development." There may also be acute symptoms if the dose is high enough. For tin in fruit drinks, the hazards are gastrointestinal: vomiting and acute gastric disturbance. The small amounts of copper that have been found in juices have led to nausea and vomiting. Higher concentrations of copper are more toxic, but have not occurred in juices or juice drinks.

The chemical contaminants that have been found in juices include sulfites, sodium hydroxide, and undeclared dyes. Sulfite-sensitive people can experience symptoms ranging from moderate-acute sensitivity reaction to anaphylactic-like shock. Victims described the health effect from sodium hydroxide in citrus punch as oral burning or irritation of the lips if in contact with the bottle neck. Multiple fruit drink products for 10 companies contained undeclared FD&C yellow # 5 (a potential allergen), which is considered a limited-acute to moderate-acute health hazard.

Other contaminants posing health hazards include glass, plastic, salt, and milk. Undeclared salt could be a health hazard to people with hypertension, heart failure, and some types of renal disease. Undeclared milk is a hazard to people with lactose intolerance or protein allergy (or intolerance). Glass particles are a danger to the mouth, throat, and gut, but the risk is small. For plastic, aspiration is the potential hazard. The people who swallowed the plastic complained of choking.

Pesticides pose many potential human health hazards. Although pesticides can be toxic in high enough doses, the residues likely to be found in fruit juices are too small to pose an acute hazard. The more likely hazards result from chronic exposure to small pesticide residues. Those residues, if consumed for many years, may be large enough to lead to chronic health problems such as cancer. The likelihood of chronic health hazards from pesticide residues in juices depends on the likelihood of long-term consumption of the contaminated product. If an excessive residue occurred rarely, the likelihood of chronic health effects would be negligible. If an excessive residue occurred as a result of normal processing practice (such as might occur with the improper use of an anti-microbial) and was likely to recur, then there would be potential chronic health effects for some consumers.

The probability that juices or juice products will contain pesticide residues depends on the amounts used on the raw product, the amounts present in the soil, and the effect of processing on pesticide residues. The levels of pesticide residues found in raw fruits have generally been well below established safety levels. In fiscal year 1994, for example, less than one percent of the fruits sampled in the FDA's pesticide monitoring program had violative residues (Food and Drug Administration 1995). Processing probably reduces residues further. For example, 98 percent of benomyl residue is removed from oranges and 71 percent is removed from apples during processing into juice (Elkins 1989). The combined effects of low residues on raw fruits and vegetables and of further reductions during processing account for the virtually absence of violative residues in fruit juices.

From fiscal year 1991 through fiscal year 1997, the FDA tested 1,196 domestic and imported fruit and vegetable juice samples; the samples came from both surveillance and compliance programs. Of the 1,196 samples, three contained violative residues of acephate. Other violative residues (class 2 -- not in compliance but not of regulatory concern) found between fiscal 1991 and fiscal 1997 included traces of acephate in one sample of watermelon juice concentrate, traces of chlorpyrifos in one sample of grape juice, and traces of methamidophos in two samples strawberry-nectarine juice and one sample of apple juice concentrate. Of the eight samples not in compliance, only three were of regulatory concern.

To estimate the potential number of excess cancers from violative acephate residues, we will assume that the samples analyzed between fiscal year 1991 and fiscal year 1997 were representative of all juices. The levels of acephate in the three violative juice samples were 0.075, 0.052, and 0.040 ppm, for an mean residue equal to 0.056 ppm (mg/liter). The fraction of samples containing measurable residues was approximately 0.0025 (3 ÷ 1196). The average residue in all juices (both violative and non-violative) would equal 0.00014 mg/liter (0.056 × 0.0025). With annual juice consumption equal to 34 liters, daily juice consumption would be 0.093 liters/day (34 liters/year ÷ 365 days/year). The mean daily intake of acephate residues in juice would equal 1.3×10^{-5} mg/day (0.00014 mg/liter × 0.093 liters). The daily intake per kilogram of body weight for a 60 kg person would be 2.2×10^{-7} mg/kg-bw/day (1.3×10^{-5} mg/day ÷ 60 kg-bw). The U. S. Environmental

Protection Agency has estimated the cancer potency of acephate to be 0.0087 (mg/kg-bw/day)$^{-1}$. The lifetime probability of cancer would be the product of potency and exposure, or 1.9×10^{-9} (0.00000022 mg/kg-bw/day × 0.0087 (mg/kg-bw/day)$^{-1}$). For a population of 260 million, the result would be about 0.5 additional cancers.

Other contaminants found in fruit and vegetable juices include suspected viral contamination, natural toxins (patulin), and mold. In one juice-related outbreak of gastrointestinal illness, the symptoms included abdominal pain, nausea, and vomiting and were characterized by abrupt onset and short duration. In another outbreak, the symptoms developed within 48 hours of drinking juice and included cramping, vomiting, diarrhea, and low-grade fever. Viral contaminants were suspected in both outbreaks, but not found. The nausea and vomiting suspected to have resulted from toxic seed material in guanabana juice began within one hour of consumption. Parts of the elderberry plant contain an alkaloid and glucose that under certain conditions can produce hydrocyanic acid. Juice made from elderberry caused gastrointestinal and neurological symptoms.

Assessing most of the hazards described in this section will not go beyond hazard identification. These hazards are irregular and unpredictable, with mostly mild outcomes. The potential adverse health effects associated with some of the hazards, such as pesticides, are great and may require monitoring by processors. Nonetheless, we found little epidemiological and product sampling evidence that juices have been contaminated with these hazards at levels sufficient to cause serious illness.

VIII. Summary

Several different questions about the morbidity and mortality associated with the consumption of fruit and vegetable juices have been shown to be potentially important. These questions include:

- What are the health hazards associated with juice consumption?
- Which processing steps are most frequently associated with the introduction of these hazards?
- What kinds of juices are most likely to contain these hazards?

The Center for Food Safety and Applied Nutrition working group has gathered and considered information and data related to these questions and will address what is known and what is not known concerning the answers to all three questions.

What are the health hazards associated with juice consumption?

The main health hazards associated with juices appear to be illnesses caused by microbial pathogens. Although other hazards -- such as pesticide residues -- are potentially serious, the estimated risks are small and no human data indicates that their presence in juices has caused serious illnesses. By contrast, we do have some human health data on illnesses and deaths resulting from consumption of juice contaminated with microbial pathogens. From 1993 through 1996, juices accounted for 447 confirmed illnesses caused by microbial pathogens, with symptoms that ranged from mild discomfort to one death (see tables 4, 5 and 6). The pathogens included *Salmonella, E. coli* O157:H7, *B. cereus*, *C. parvum*, and an unknown microbial pathogen. It is likely that the 447 reported cases represented a very small fraction of the total cases that occurred, because in most instances victims either do not seek medical treatment, or -- when they do -- their illnesses are not diagnosed, misdiagnosed, not reported, or fail to be associated with their consumption of juice.

Which processing steps are most frequently associated with the introduction of these hazards? We found little data available to answer this question. Farms and orchards appear to account for most primary sources of contamination; in fact, many pathogens, such as *E. coli* O157: H7, appear to be common in the rural environment, and therefore some of the raw product will be contaminated. Although little evidence has been accumulated to indicate where and how pathogens are most likely to be introduced, the following possible causes of contamination (which occur during the growing and harvesting steps) have been suggested: use of dropped fruit, proximity of livestock or wild animals, contaminated ground water, and contaminated humans.

Washing the exterior of the fruits effectively removes the contamination only if the washing is sufficiently thorough and the product interior has not become contaminated. If heat processing (or some similar effective step) is carried out properly, little risk from pathogens should remain in the finished juice product (with the exception of the *B. cereus* toxin, which can survive ordinary juice pasteurization times and temperatures). In the past, acidity and water activity prevented the survival of microbial pathogens in non-heat-treated juice. In recent years, new microbial strains have emerged that have demonstrated their ability to survive in at least some relatively acidic juices.

What kinds of juices are most likely to contain these hazards? This question can be answered at least qualitatively. Non-heat-treated juices accounted for 339 (76 percent) of the 447 cases reported in 1993-1996, while accounting for slightly more than one percent of juice consumption. In addition, the illnesses associated with non-heat-treated juices tended to be more severe than those associated with heat-treated juices (see table 6). We therefore conclude that non-heat-treated juices are much more hazardous than heat-treated juices.

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