J–105 [Revised]

From Ranger, TX; via McAlester, OK; Razorback, AR; Springfield, MO; Bradford, IL; to Badger, WI.

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J–131 [Revised]

From San Antonio, TX, via INT San Antonio 007° and Ranger, TX, 214°T (208°M) radials; Ranger; Texarkana, AR; Little Rock, AR; to Pocket City, IN.

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J–181 [Revised]

From Ranger, TX; Okmulgee, OK; Neosho, MO; INT Neosho 049° and Bradford, IL, 219° radials; to Bradford.

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Issued in Washington, DC, on August 21, 1997.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 97–22974 Filed 8–27–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket No. 97N–0296]

Fruit and Vegetable Juice Beverages: Notice of Intent to Develop a HACCP Program, Interim Warning Statement, and Educational Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is announcing a comprehensive program to address the incidence of foodborne illness related to consumption of fresh juice and to ultimately address the safety aspects of all juice products. This document informs consumers, juice processors, State and local officials, and other interested persons of FDA's plans to publish two proposals and to initiate several educational programs to minimize the hazards associated with fresh juice. This document will permit all interested persons to take advantage of the guidance provided by the upcoming proposals as quickly as possible, e.g., in time for the 1997 ''fresh apple cider'' season.

DATES: Submit written comments at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23 Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

Escherichia coli O157:H7 has been recently implicated as a source of a number of foodborne disease outbreaks. During the last few years, several States have reported outbreaks of *E. coli* O157:H7 illness as a result of consumption of apple juice and cider that were not pasteurized or otherwise treated to destroy pathogens (Refs. 1, 2, and 3). Symptoms have ranged from diarrhea to hemolytic uremic syndrome. In October 1996, the Seattle-King County Department of Public Health and the Washington State Department of Health reported an outbreak of *E. coli* O157:H7 infections associated with consumption of unpasteurized apple juice that occurred in three western States and British Columbia and resulted in at least 66 cases of illness and the death of one child (Refs. 2 and 4).

Pathogens other than *E. coli* O157:H7 present in apple and other types of juice and juice products also have been documented as causing foodborne illness. There are reported outbreaks attributable to *Salmonella typhimurium and Cryptosporidium* in apple cider (Refs. 3, 5, and 6), and *Vibrio cholerae* in coconut milk (Ref. 7). In addition, there are reports of illness from consumption of unpasteurized orange juice contaminated with *S. hartford* (Ref. 8), orange juice drink contaminated with *S. agona* (Ref. 9), orange juice contaminated with *Bacillus cereus* (Ref. 10), and home-made carrot juice contaminated with *Clostridium botulinum* (Ref. 11).

Both fruit and vegetable juices have been vehicles for outbreaks of foodborne illness. Although fruit juice is acidic and thus inhibitory to the growth of most microorganisms, fruit juices, rather than vegetable juices, have been the source of most juice-associated outbreaks. The evidence also suggests that the groups at greatest risk of life-threatening illness are children, the elderly, and persons with compromised immune systems.

Illnesses caused by hazards other than microbial contamination have also been associated with foods, including juice. From 1990 to 1996, there has been one outbreak and 11 recalls of fruit juice or beverages containing fruit juice (Refs. 12 and 13). Ingestion of toxic metals as well as poisonous parts of the plants used to make the juice have been cited as the cause of some juice related illness.

Five recalls between 1990 and 1995 of fruit juices or beverages containing fruit juice were because of the presence of food ingredients that were inadvertently added to the product, not declared on the label, or not suitable for that food (Ref. 13). Food ingredients involved with these recalls were natamycin, sulfites, FD&C yellow No. 5, and salt.

Since 1991, there have been five recalls of juice products because of improper sanitation procedures or faulty equipment that resulted in cross-contamination with ingredients from other foods, minerals such as copper, glass, or other hazardous materials. These outbreaks and recalls demonstrate that juice and juice beverages may be susceptible to many hazards.

The October 1996 apple juice outbreak from *E. coli* O157:H7, and the agency's concern that the current regulatory program relative to fresh juice and juice products may not be adequate to ensure the production of safe juice products, persuaded FDA to gather information to help address these problems. FDA held a public meeting on December 16 and 17, 1996, to discuss the current state of the science and to review the technological and safety factors relating to the production and distribution of fresh juices. The agency was interested in learning about all aspects of juice production and distribution in an effort to consider how FDA's regulatory program should be revised, and whether additional measures are needed to reduce the risk of future outbreaks.

Experts from industry, academia, and the regulatory and consumer sectors presented information on illnesses and the epidemiology of outbreaks arising from contaminated juices; current concerns with emerging pathogens; the *E. coli* O157:H7 outbreak in October 1996 caused by contaminated unpasteurized apple juice; procedures for processing juices; and new and existing technologies to decrease or eliminate the number of pathogens or other contaminating microorganisms.

FDA received over 180 comments, most of which concerned apple juice specifically. Many comments pertained to juices in general and some referred only to apple juice, apple cider, or citrus juices. Most comments were concerned with changes in processing to improve the safety of juices. Among the changes recommended were requiring pasteurization of juices, requiring a Hazard Analysis and Critical Control Point (HACCP) program, and

establishing current good manufacturing practices (CGMP's) in juice processing.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) subsequently recommended to FDA, among other things, that HACCP and safety performance criteria should form the general conceptual framework for assuring the safety of juices, and that control measures should be based on a thorough hazard analysis. Furthermore, the NACMCF recommended that a mandatory HACCP program be established, and that processors implement and strictly adhere to industry CGMP's. The NACMCF also recommended that industry education programs be developed that address basic food microbiology, the principles of cleaning and sanitizing equipment, CGMP's, and HACCP.

The information FDA obtained through the public meeting, as well as the recommendations of the NACMCF, clearly suggest that new measures are necessary to ensure that juice is safe. The virulence of new pathogens, such as *E. coli* O157:H7, and the risk of severe illness associated with these pathogens, especially for children, the elderly, and persons with weakened immune systems, create a need for prompt, active intervention. The agency has considered the recommendations provided in the comments and by the NACMCF and has developed a proposed strategy for ensuring juice safety. This proposed strategy involves addressing both the immediate goal of reducing the risk of foodborne illness associated with juice products and the long-term goal of ensuring that juice products are safe. This proposed strategy, as discussed below, involves a three-pronged approach that includes a mandatory HACCP program, label warning statements, and educational programs targeted at the industry and consumers.

II. Mandatory HACCP Program

The agency has considered several alternatives recommended in the comments in determining whether to initiate rulemaking on a mandatory HACCP program for some or all juice products. The alternatives being considered include: (1) Increasing the frequency of FDA's inspection of juice manufacturers, as well as increasing agency sampling, laboratory analysis, and related regulatory activities; (2) issuing CGMP's or sanitation standards to increase the safety of juices; and (3) mandating pasteurization or other equivalent treatment of juices.

At this point, the agency believes, based on available data, that a mandatory HACCP program is the most effective means of controlling microbiological, as well as chemical and physical hazards that may occur during juice processing, and that, therefore, such a program may be necessary for the safe and sanitary production of fruit and vegetable juices. Accordingly, the agency intends to propose a regulation that will mandate a HACCP program for some or all fruit and vegetable juice products. FDA intends to propose that some or all juice processors have and implement a written HACCP plan whenever a hazard analysis reveals that one or more food hazards are reasonably likely to occur, and that a HACCP plan be specific to each location where juice is processed by that processor. Thus, the agency is considering that implementation of a HACCP program will be the primary, long-term control measure for pathogens and other safety concerns related to the production and distribution of juice products.

Under a mandatory HACCP program, FDA would propose a phase in period for implementation of HACCP plans for juice products. The phase in approach will permit the regulated industry time to develop a HACCP plan, accomplish the training of personnel, and adjust its activities to include necessary HACCP activities.

The forthcoming HACCP proposal will fully discuss all of the issues surrounding the safety of fruit and vegetable juices raised in this document.

III. Label Warning Statements

Although FDA has tentatively concluded that additional steps are necessary to ensure that juices are safe, the agency recognizes that rulemaking and implementation of a HACCP program are time consuming, and that a HACCP program for some or all juices would not likely be fully implemented for several years. In light of these facts, and the immediate concerns raised by the potential for foodborne illness from consumption of juice products neither processed in accordance with an established HACCP plan, pasteurized, nor otherwise treated to prevent or eliminate the presence of harmful bacteria that may be present, the agency sees a need for immediate action to ensure that consumers, particularly those at greatest risk, are informed of this potential hazard. This information can be conveyed through labeling, which can be effected by industry much more quickly than it can implement a HACCP program.

Consequently, the agency is considering proposing that the labels and labeling of some or all juice products not specifically processed to prevent or eliminate the presence of harmful bacteria bear a warning statement informing consumers of the risk of illness associated with consumption of the product. The agency anticipates that this will be an interim measure, until requirements for processing juice products under HACCP principles are fully implemented. The agency notes that it is considering providing that interventions that have been validated to achieve a cumulative 5-log reduction in *E. coli* O157:H7 or other pathogens would obviate the need for a warning label. Based on available information, however, the agency considers pasteurization the only process validated to meet this standard at this time. However, the agency solicits comments on other ways to achieve this reduction. Thus, in the absence of a validated HACCP plan, the agency anticipates that a warning statement will appear on some or all unpasteurized juice products.

Consumer research data available to the agency suggest that consumers need clear and concise information about the nature and magnitude of the hazard in the food to understand a warning statement, and that certain elements are essential to ensure that the warning statement is effective (Ref. 14). These elements include statements describing the hazard, explaining why the hazard is present, advising how to avoid or alleviate the hazard, and identifying the group at risk. Depending on the type of food and the nature of the hazard, each of these elements may not be essential in developing an effective warning statement.

To inform consumers effectively of the potential hazard associated with some or all juice products, FDA has tentatively concluded that three of the elements listed above would need to be reflected in the label warning statement. The warning statement for unpasteurized juice products could contain: (1) A statement of the hazard, that is, a statement about the potential presence of bacteria that can cause serious illness; (2) a statement explaining why the hazard is present, that is, a statement that the labeled product has not been processed or treated to destroy the harmful bacteria; and (3) a statement identifying the group at risk, that is, that evidence suggests that children, the elderly, and persons with weakened immune systems are at greatest risk of serious illness from exposure to harmful bacteria in juice and juice products. The agency will request comments on whether the warning statements should also include a fourth element, advising that at-risk consumers avoid the product.

The consumer research data also showed that the first sentence of a warning statement is likely to influence a consumer's decision as to whether to continue reading the rest of a warning statement. Therefore, the agency intends to propose that the first sentence of the warning statement clearly state the hazard, i.e., that juice may contain pathogens known to cause serious/life-threatening illness. The agency recognizes, however, that there may be several ways to incorporate the essential elements into the warning statement. For example, the following model statements incorporate the three essential elements that FDA has tentatively concluded would need to be reflected in the label warning statement, but they communicate the information using different wording.

1.**WARNING:** Unless specifically processed, some juices may contain harmful bacteria known to cause serious illness. This product has not been specifically processed to destroy such bacteria. The risk of life-threatening illness is greatest for children, the elderly, and persons with weakened immune systems.

2.**WARNING:** Some juices have recently been found to contain harmful bacteria known to cause life-threatening illness. This product has not been specifically processed to destroy such bacteria. Children, the elderly, and persons with weakened immune systems should avoid this product.

3. **WARNING:** This product has not been pasteurized and therefore may contain harmful bacteria which can cause serious illness in children, elderly, and persons with weakened immune systems.

The second statement includes the fourth element, advising the at-risk consumer to avoid the product. FDA believes that any of these statements would inform consumers adequately of the potential risk of foodborne illness associated with the juice product. Accordingly, FDA is considering proposing statements such as these warning statements for juice products not pasteurized or otherwise treated to prevent or eliminate the presence of harmful bacteria. However, the agency recognizes that because these statements are untested, there may be a more effective way to alert consumers to the potential hazard.

The agency is mindful that manufacturers may wish to include optional language on the label. For example, in addition to the information required by the essential elements, information describing the product as ''unpasteurized'' may be included. Handling instructions to ensure the safety of the product also may be included, e.g., ''boil product prior to serving.'' Similarly, manufacturers of pasteurized juice products may wish to include information on the label of their product informing the consumer that the product has been pasteurized. Because such information may be helpful and convenient for consumers searching for pasteurized juices, the agency encourages manufacturers of pasteurized juices to include the term ''pasteurized'' on the product label. In its labeling proposal, FDA will request comments on whether such additional information should be required. The agency notes, however, that consistent with the requirements for all label statements, any optional information must be truthful and not misleading.

Consistent with the placement and prominence requirements of other warning statements, FDA is considering proposing that the statement appear prominently and conspicuously on the information panel of the immediate container of the product, in type size no less than one-sixteenth of an inch, and set apart from other printed matter on the information panel by hairlines in the configuration of a box. In addition, the agency is considering proposing that the word ''**WARNING**'' be in capital letters and in bold type.

The agency may conduct focus group research to evaluate consumer understanding of the proposed warning messages and to ensure that the messages are not misleading. The results of any focus group research would be considered by the agency in arriving at warning statements included in a final regulation.

In its proposal, the agency will discuss and solicit comment on its tentative decision to require an interim warning statement on unpasteurized juices, its justification for the required elements of the warning statement, and its tentative conclusion that the proposed statements adequately inform the consumer of the potential risk associated with the juice product. In addition, the agency is considering proposing a sunset provision for the mandatory warning statement.

Given the severity of the outbreaks with fresh apple juice that occurred during the 1996 season, the agency strongly encourages processors of unpasteurized apple juices to immediately and voluntarily label their products or provide point of purchase information with any of the model statements or a similar statement that includes the essential elements discussed above. Although the agency has particular concern about the potential for foodborne illness associated with apple juice because of the documented contamination with *E. coli* O157:H7, it encourages manufacturers of all types of juice to place warning labels on their products that have not been pasteurized. Such labeling may be accomplished by the use of stickers, placards, brochures, etc.

Further, FDA is aware that some State authorities are considering the steps that they need to take to protect consumers. The agency encourages State and local officials to consider the information in this document as guidance as they contemplate requirements for untreated juice products during the 1997 season.

The agency is considering whether to include some or all fruit and vegetable juice products that have not been pasteurized or otherwise specifically processed to prevent or eliminate the presence of harmful bacteria in any future proposal on label warning statements. The agency expects that any final rule on a mandatory warning statement will be issued prior to the start of the 1998 ''fresh apple juice/cider'' season.

IV. Educational Program

FDA's primary goal is to ensure that the food supply is safe and that consumers are protected to the greatest extent possible from foodborne illness and other adverse reactions resulting from food consumption. The rulemakings that FDA intends to initiate on HACCP and on the interim warning statement should help to accomplish this goal with respect to juice products. Nevertheless, the benefits of these rulemakings will be enhanced if, in conjunction with them, FDA initiates educational programs aimed at industry and consumers. Consistent with the NACMCF recommendations, the agency believes that industry education programs addressing basic food microbiology, the principles of cleaning and sanitizing equipment, CGMP's, and HACCP will greatly assist juice processors in developing and implementing an effective HACCP plan. Given the severity of the outbreaks with unpasteurized apple juice and cider and the fact that final rules cannot be in place by the 1997 fresh cider season, the agency will use the education programs to encourage the industry to label their products voluntarily to advise consumers of the risks associated with fresh juice. In addition, educating consumers about the risks to certain populations associated with the consumption of untreated juice and the potential for the presence of pathogens and other hazardous substances will help to ensure that consumers fully understand the importance of label

statements and the significance of the appearance of warning statements on certain juice products but not on others.

The agency intends to involve State and local officials in its education initiative because it is often the State or local official who is in direct contact with the farmer or juice processor. Thus, State and local officials can play a significant role in educating and assisting juice manufacturers and consumers in understanding the public health concerns associated with consumption of untreated juice products and in developing measures to reduce the risk.

To meet its educational objectives, FDA intends to: (1) Enlist the aid of State and local officials, industry representatives, trade associations, and consumer groups in coordinating consumer and industry educational outreach programs; (2) use FDA field public affairs specialists to educate consumers and health professionals through lectures, meetings, and local media spots; (3) use FDA's home page on the World Wide Web to alert consumers to the potential hazard; (4) hold public meetings to discuss the issues raised in the impending proposals as well as the educational programs discussed in this document; (5) distribute ''Dear Consumer'' letters to targeted consumer groups; (6) use the FDA CFSAN information line to relay information to consumers and health professionals about the public health concern associated with untreated juice; (7) distribute camera-ready English and Spanish articles and English radio scripts and video news releases to the news media nationwide in September 1997 to coincide with the National Food Safety Education Program and ''Back to School'' program; and (8) distribute letters and articles to State and local officials.

V. Conclusion

As outlined in this document, FDA has developed a proposed comprehensive strategy to address the public health concerns associated with consumption of fresh juice and juice products not specifically treated to prevent or eliminate the presence of pathogens. The agency invites comment on the appropriateness of its strategy on the guidance contained in this document and on whether additional or alternative regulatory or nonregulatory measures are necessary to adequately protect consumers. Comments suggesting additional or alternative measures should explain why such measures are needed and suggestions on how to implement the measure.

In addition, the agency solicits comments on the specific wording of the warning statement to ensure that the final warning statement adequately conveys to consumers the risk of illness associated with consumption of the juice product. Furthermore, the agency solicits comments on whether to include all or some fruit and vegetable juice products that have not been pasteurized or otherwise specifically processed to prevent or eliminate the presence of harmful bacteria in any future proposal on HACCP or label warning statements.

Because the details of this strategy will be discussed more fully in any future proposals, commenters may choose to wait until that time to respond. However, the agency will consider comments received within 15 days of publication of this notice prior to publication of any proposed rule. Because of time constraints, the agency may not be able to consider comments received after this date, but these comments will be considered as part of the public rulemaking record associated with any proposal.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Besser, R. E., S. M. Lett, J. T. Weber, M. P. Doyle, T. J. Barrett, J. G. Wells, and P. M. Griffin, ''An Outbreak of Diarrhea and Hemolytic Uremic Syndrome from *Escherichia coli 0157:H7* in Fresh-pressed Apple Cider,'' *Journal of the American Medical Association,* 269(17):2217:2220, 1993.

2. Centers for Disease Control and Prevention, ''Outbreak of *Escherichia coli 0157:H7* Infections Associated with Drinking Unpasteurized Commercial Apple Juice—British Columbia, California, Colorado, and Washington, October 1996,'' *Morbidity and Mortality Weekly Report,* 45(44):975, 1996.

3. Centers for Disease Control and Prevention, ''Outbreaks of *Escherichia coli 0157:H7* Infection and Crytosporidiosis Associated with Drinking Unpasteurized Apple Cider—Connecticut and New York, October 1996,'' *Morbidity and Mortality Weekly Report,* 46(1):4–8, 1997.

4. National Advisory Committee on Microbiological Criteria for Foods—Fresh Produce Subcommittee Proceedings, December 16, 1996.

5. Centers for Disease Control, ''*Salmonella typhimurium* Outbreak Traced to a Commercial Apple Cider—New Jersey,'' *Morbidity and Mortality Weekly Report,* 24:87–88, 1975.

6. Millard, P. S., K. F. Gensheimer, D. G. Addiss, D. M. Sosin, G. A. Beckett, A. Houck-Jankoski, and A. Hudson, ''An Outbreak of Crytosporidiosis from Fresh-pressed Apple Cider,'' *Journal of the American Medical Association,* 272(20):1592–1596, 1994.

7. Centers for Disease Control and Prevention, ''Cholera Associated with Imported Frozen Coconut Milk—Maryland, 1991,'' *Morbidity and Mortality Weekly Report,* 40(49):844–845, 1991.

8. Centers for Disease Control and Prevention Memorandum from Kim A. Cook, M.D. to Steve Thacker, M.D., October 1, 1995.

9. FDA Recall Data Memorandum, Dirk J. Mouw to Raymond P. Mars, June 2, 1992.

10. FDA Recall Data Memorandum, M. Anthony Abel to Ronald E. Joyce, March 21, 1994.

11. Memorandum of Telephone Conversation between Debra Street, Ph.D., FDA, and P. Walker, Washington State Department of Health, January 15, 1997.

12. Memorandum of Telephone Conversation between Debra Street, Ph.D., FDA, and Dr. K. Hendricks, Texas State Department of Health, January 16, 1997.

13. FDA Memorandum to File, B. Timbo, Ph.D., July 14, 1997.

14. FDA Memorandum, Alan S. Levy, Ph.D. to Kenneth Falci, Ph.D., June 26, 1997.

VII. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this document at any time. As noted above, the agency will consider comments received by September 12, 1997, prior to publication of any proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22977 Filed 8–25–97; 4:44 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

DEPARTMENT OF TRANSPORTATION

Coast Guard

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900–AF85

Veterans Education: Suspension and Discontinuance of Payments

AGENCIES: Department of Defense, Department of Transportation (Coast Guard), and Department of Veterans Affairs.

ACTION: Proposed rule.