

March 1, 2000

Hon. Jane Henney, MD
Commissioner of Food and Drugs
Food and Drug Administration
5600 Fisher Lane, Room 16-70
Rockville, MD 20857

Re: Hazard Analysis and Critical Control Point System; Procedures for the Processing of Apple Cider, Docket No. 97N-0511, 63 Fed. Reg. 20,450 (April 24, 1998); 63 Fed. Reg. 24,254 (May 1, 1998) and 64 Fed. Reg. 65,669 (November 23, 1999).

Dear Commissioner Henney:

The Office of Advocacy of the U.S. Small Business Administration (SBA) was established by Congress pursuant to Pub. L. No. 94-305 to advocate the views of small business before federal agencies and Congress. Advocacy is also required by section 612(a) of the Regulatory Flexibility Act (RFA)¹ to monitor agency compliance with the RFA. In addition, the Chief Counsel of Advocacy is authorized to appear as *amicus curiae* in regulatory appeals from final agency actions, and is allowed to present views with respect to compliance with the RFA, the adequacy of the rulemaking record with respect to small entities, and the effect of the rule on small entities.² On March 28, 1996, President Clinton signed the Small Business Regulatory Enforcement Fairness Act (SBREFA)³ which made a number of significant changes to the RFA, including the provision to allow judicial review of agencies' compliance with the RFA.⁴

FDA has published a number of *Federal Register* notices regarding the above-cited regulation—a proposed rule, a separate analysis of impacts, and a notice reopening the comment period (which included a solicitation for comments from small businesses on the impact of the proposed regulation). The regulations are supposed to ensure the safe and sanitary process of fruit and vegetable juices and juice products. In addition to labeling requirements (currently in effect) that notify consumers of the hazards associated with drinking unpasteurized juices, the proposed regulation will also mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles⁵ to the processing of these foods.

The Office of Advocacy commented on the labeling provisions of the regulation on June 10, 1998, and also met with FDA officials (including Richard Williams with the Center

¹ 5 U.S.C. § 601 et seq.

² *Id.*

³ Pub. L. No. 104-121, 110 Stat. 857 (1996).

⁴ 5 U.S.C. § 611.

⁵ HACCP is a preventative system of hazard control that seeks to achieve pathogen reduction during food processing. The proposed Juice HACCP proposal was modeled after the existing HACCP programs for meat, poultry and seafood where potential hazards and control measures are identified prior to the development of pathogens.

for Food Safety and Applied Nutrition) to discuss the regulation. In addition, the Office of Management and Budget consulted Advocacy on the impact of the regulation. During the informal consultation, Advocacy expressed concern about the somewhat arbitrary nature of the proposed 5-log pathogen reduction standard and its impact on small business.

Although the comment period for the HACCP regulation has expired, the Office of Advocacy wishes to share its concerns about the regulation with FDA, as well as some suggestions to reduce burden that were recently advanced by industry representatives.

FDA is proposing a 5-log (99.999%) reduction in pathogens in fresh juice. It does not appear that FDA has adequately considered whether a lower level (e.g., 4-log reduction) would be adequate for the purpose of reducing health risks. Using today's approved technology, the only realistic way to achieve the proposed reduction is to pasteurize all juices. Therefore, the small businesses that cater exclusively to customers that want unpasteurized juice will no longer be able to provide this type of product. Moreover, switching to pasteurization would involve major expenses—over \$18,000 in the first year according to FDA's own estimates.

Although the juice HACCP proposal was modeled after the programs for meat and poultry, the juice proposal goes beyond the requirements for meat and poultry in terms of the 5-log reduction. The Centers for Disease Control report that, for the past ten years, 51% of E. coli outbreaks were attributable to meat and milk products, and only 19% were attributable to a miscellaneous category that included fresh juices (and mayonnaise, lettuce, sandwiches, etc.). Of the outbreaks attributable to fresh juices, most were likely caused by apple cider. The juice proposal, therefore, does not seem to be a proportional regulatory response to the public health risk associated with unpasteurized juice.

In addition to the 5-log reduction, FDA is proposing that juice processors evaluate food hazards like the presence of undeclared allergens. This means that processor who use the processing equipment for more than one process (e.g., milk and juice, or two different kinds of juice) will need to consider possible allergies to the substances not declared on the ingredient labels. Advocacy is not aware of any other food processing regulations with this type of requirement. It is not clear why a food product should be deemed hazardous when it is free of pathogens and generally safe for the public. Proper sanitation, which is part of a good HACCP plan, should be adequate to protect consumers against possible allergens.

Also, the proposal requires processors to test for appropriate pesticide levels. Some of the burden for this type of testing could be passed on to growers. After all, processing operations do not add pesticides. Pesticide testing is not required for meat and poultry HACCP, yet animals could have consumed grains containing pesticides. Moreover, this proposal applies only to fresh juices. Are other juices and/or foods subject to pesticide testing? The primary focus of the regulation should be pathogen reduction.

Apple growers have reported to the Office of Advocacy that extreme weather conditions like flooding and drought have caused a severe drop in sales. Growers have also reported that the dumping of below-cost apple juice concentrate from foreign countries has caused economic injury to their industry. In addition, growers have raised concerns that FDA has underestimated costs—particularly in those regions with higher utility, physical plant and wage costs. The point is that these already financially burdened businesses cannot afford to pasteurization equipment. Although the regulation states that businesses will have flexibility in how they must comply, the reality is that pasteurization is the only currently approved manner in which to achieve the 5-log reduction.

At least one organization representing apple cider producers has suggested a couple of alternatives that may reduce the burden associated with this regulation. First, allow the measurement of pathogen reduction to begin after apples have been picked, before pressing; and enable processors to count methods such as washing, use of potable water, and sanitation of equipment in determining whether the pathogen reduction standard has been achieved. In other words, measuring pathogen reduction after pressing limits the methods of treatment. If the measurement of pathogens takes place prior to pressing, then methods like washing can effectively eradicate most external pathogens.

Also, the industry recommends that FDA move forward with the approval process on other technologies like (less expensive) ultraviolet (UV) light treatment so that the industry truly will have options—other than pasteurization—to help them achieve the desired pathogen reduction standard. Industry representatives have stated that if the HACCP regulation is finalized after approving the use of UV light, and a grace period sufficient for UV light equipment to become fully available is permitted, then compliance would be less burdensome.

The Office of Advocacy urges FDA to consider these comments and suggestions. In addition, the Office of Advocacy requests that the current exemption for retailers and restaurants be maintained. If the proposal is implemented as written, all juices—regardless of the relative risk they impose on health and safety—will have to be pasteurized. The irony of this result is that elaborate HACCP regulation probably would not be necessary if all juices were pasteurized. Thank you for your attention to this matter. Please do not hesitate to contact our office if you have any questions, 202-205-6533 or 6532.

Sincerely,

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