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Guidance for Industry

Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory

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**U.S. Department of Health and Human Services
Food and Drug Administration
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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This guidance is intended to advise food manufacturers that once a boil-water advisory has been issued they should stop using the water subject to the advisory until the water again meets the applicable federal and state drinking water quality standards. Further, this guidance is intended to assist food manufacturers in evaluating food that already was produced with water subject to the advisory.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Boil-water advisories are public announcements by local water authorities advising the public to boil their tap water for drinking and other human consumption uses, to protect public health from waterborne infectious agents that could be or are known to be present in drinking water. Such advisories are issued for a variety of reasons, including broken water mains and flooding that adversely impacts water treatment facilities. For example, on May 1, 2010, water service to 30 Massachusetts Water Resources Authority (MWRA) customer communities (serving approximately 2 million residents) was interrupted by a major break in a 120-inch diameter MWRA pipe that transports water to communities east of Weston, Massachusetts. MWRA later reported that the damaged section had been repaired and passed its load test, and the system is distributing water to all communities. In response to this major water break, the President issued

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition in cooperation with the Office of the Center Director at the U.S. Food and Drug Administration.

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an emergency declaration (FEMA-3312-EM) to facilitate Federal assistance to the Commonwealth of Massachusetts for emergency protective measures. On May 4, 2010, the boil-water advisory was lifted, and the Governor of Massachusetts announced that water was once again clean and safe for all purposes. FDA worked in concert with the United States Department of Agriculture and MWRA to address issues related to the affected food industry.

III. Discussion

Once a boil-water advisory has been issued, food manufacturers should stop using the water subject to the advisory until the water again meets the applicable federal and state drinking water quality standards. In addition, any food produced with water subject to the advisory should be evaluated. FDA is providing recommendations to assist food manufacturers in evaluating such food.

When a boil-water advisory is issued, it is assumed that bacterial contamination may have occurred. Unless the boil-water advisory is due to a subterranean break in a water line, one should assume that *Cryptosporidium*, a microbial parasite, may also be present. Heat treatment and, where applicable, filtration can be used to reduce or eliminate the risk from this contamination. More heat is needed to inactivate *Cryptosporidium*, which has greater heat resistance than vegetative cells of bacterial pathogens of concern. Bacterial cells are smaller than those of *Cryptosporidium*. Thus, if 1 μm absolute filtration (International Bottled Water Association, 2001) is used to remove *Cryptosporidium* oocysts from water or other beverages, additional filtration or other treatments is needed for vegetative cells of bacterial pathogens. Disinfectants such as ozone, hypochlorite, chlorine dioxide or UV used in conjunction with 1 μm absolute filtration are sufficient to address both *Cryptosporidium* and vegetative cells of bacterial pathogens. *Cryptosporidium* is resistant to many chemical disinfectants, including chlorine (Donnelly and Stentiford, 1997).

Use of Water in Heated Foods

If water subject to the advisory was used as an ingredient in food and the product has subsequently been adequately heat treated (e.g., pasteurized, retorted, baked, boiled, simmered) the food does not present a risk with respect to the water used. Based on data available to FDA for reducing *Cryptosporidium* in water, milk and cider (Deng and Cliver, 2001; Fayer, 1994; Harp et al., 1996) FDA recommends heat treatment for 15 seconds at 161°F. For juice products, the FDA Juice HACCP Hazards and Control Guidance (FDA, 2004) recommends heat treatments that achieve 160°F for 6 seconds or the equivalent in products with a pH 4.0 or less.

If water subject to the advisory was used as an ingredient in food and the food was not heat treated by the food manufacturer, the product may present a risk to the consumer and should not be distributed unless FDA, in consultation with the affected state, determines that the risk is minimal and can be controlled with ordinary consumer cooking practices.

Use of Water in Frozen Foods

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If water subject to the advisory was used as an ingredient in food and the product has been frozen for the following times and temperatures, the food does not present a risk with regard to the water used (Fayer and Nerad, 1996):

- 5 to 14°F for 168 hours (7 days)
- -4°F for 24 hours

Use of Water in Ice, Bottled Water, or Ready-To-Eat Foods

Because of the possible presence of *Cryptosporidium* or bacterial pathogens, water subject to a boil-water advisory should not be used for ice, bottled water or ready-to-eat (RTE) foods unless it is heat treated (e.g., 15 seconds at 161°F) or, in the case of water used for ice, bottled water, or other beverages, filtered. Filters that have a pore size of 0.2 to 0.3 µm absolute will provide adequate reduction of both vegetative cells of bacterial pathogens and *Cryptosporidium*; a 1 µm absolute filter (to achieve 99.9% removal, e.g., a filter that meets NSF Standard 53) will remove *Cryptosporidium* but not bacterial pathogens.

Use of Water for Cleaning

If water subject to the advisory was used to clean equipment, utensils, or food contact surfaces, followed by a sanitizer, there is some risk from *Cryptosporidium* for equipment that has been cleaned in place and that contains residual water that may be incorporated into product that is not heat treated or filtered. Food made with such equipment should not be released to the consumer unless the product has been heated or filtered as noted above to reduce the risk. For other equipment where water drains off, e.g., conveyor belts, because of low levels of *Cryptosporidium* and minimal transfer, there is minimal risk of transfer to foods produced on the cleaned and sanitized equipment, even if the sanitizer has limited efficacy against *Cryptosporidium*.

Although sanitizing chemicals may have limited efficacy, hot water sanitization can effectively reduce pathogens on equipment. If the temperature of the equipment cannot be brought to 161°F for 15 sec, lower temperatures for longer times can be used effectively (e.g., the temperature achieved on the equipment reaches $\geq 148^\circ\text{F}$ for 5 min).

Use of Water for Hand Washing

If water subject to the advisory was used for hand washing, there is minimal risk of transfer to food if the employees washed and sanitized their hands and wore gloves before handling the food. Employee personnel practices should limit bare hand contact with RTE foods.

Use of Water for Other Purposes

If water subject to the advisory was used where there was no contact with food and food contact surfaces, e.g., washing the floors, there is minimal risk of transfer to food.

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

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1. Deng, M.Q. and D.O. Cliver 2001. Inactivation of *Cryptosporidium parvum* oocysts in cider by flash pasteurization. *J. Food Protection* 64: 523-527.
2. Donnelly, J.K., and E.I. Stentiford. 1997. The *Cryptosporidium* problem in water and food supplies. *Lebensm.-Wiss. u.-Technol.* 30: 111 - 120.
3. Fayer, R. 1994. Effect of high temperature on infectivity of *Cryptosporidium parvum* oocysts in water. *Appl. Env. Microbiol.* 60: 2732-2735.
4. Fayer, R. and T. Nerad. 1996. Effects of low temperatures on viability of *Cryptosporidium parvum* oocysts. *Appl. Env. Microbiol.* 62: 1431-1433.
5. FDA. 2004. Guidance for Industry; Juice HACCP Hazards and Controls Guidance, First Edition.
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Juice/ucm072557.htm> (Accessed May 4, 2010).
6. Harp, J.A., R. Fayer, B.A. Pesch and G.J. Jackson. 1996. Effect of pasteurization on infectivity of *Cryptosporidium parvum* oocysts in water and milk. *Appl. Env. Microbiol.* 62:2866-2868.
7. International Bottled Water Association. February, 2001. Plant Technical Reference Manual, Chapter 4 Water Treatment and Processing.