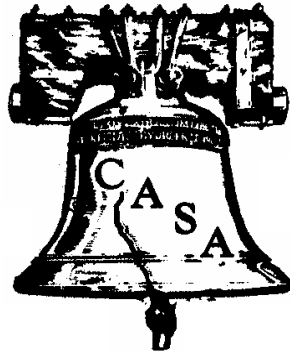


# THE BELL RINGER

THE NEWSLETTER OF THE PHILADELPHIA CONFERENCE OF THE  
CENTRAL ATLANTIC STATES ASSOCIATION OF FOOD AND DRUG

WINTER 2007



## THE PRESIDENT'S MESSAGE

Once again, winter is here. The holiday meeting was very interesting for all members. The meeting topics involved basic foundations of pest control and mold identification and remediation. As always, thank you to those who brought canned foods for our annual food drive, which were donated to the Philadelphia Food Bank.

The Executive Board is looking to compile a list of meeting topics, speakers, and locations that would be of interest to our members. If you have a topic of interest, a potential speaker or a proposed meeting location, please email this information to one of the Executive Board members.

We are always looking for members to become involved with committees. Since there are numerous committees to choose from, one of them may be of interest to you. If you would like to become involved on any committee or would like further information on the different committees, please feel free to e-mail me at [bernard.finkel@phila.gov](mailto:bernard.finkel@phila.gov) . Lastly, if you cross paths with someone who might find our organization useful, please refer them to anyone on the Executive Board or the C.A.S.A website ([www.casafdo.org](http://www.casafdo.org) ) for further information.

*Sincerely,  
Bernie Finkel*



# Federal News

## **FDA Awards Grants to Further Food Safety Part of efforts outlined in agency's new Food Protection Plan**

The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) today announced the award of three lab grants, designed to boost the food screening capabilities and spot radioactive material in food, resulting from deliberate or accidental contamination. These labs are part of the Food Emergency Response Network (FERN).

The three-year grants provide \$250,000 a year for supplies, personnel, minor facility upgrades and training. Recipients of the grants are the Texas Department of State Health Services Laboratory, the New York Health Research/New York Department of Health, and the Wisconsin State Laboratory of Hygiene.

FDA's ORA will expand its testing program to address the threat to food safety through radiological terrorism events. ORA has developed radiological screening and analysis methodologies used to evaluate foods and food products.

The grants are targeted toward enhanced detection of radiological contamination and thus enhance the nation's overall capability to rapidly detect and respond to deliberate attacks on the food supply.

The grant awards further expand the FDA's ability to promote the integrated strategy for protecting the nation's food supply through the three core elements of prevention, intervention, and response, as outlined in the agency's Food Protection Plan. These funded labs will be involved in food defense surveillance testing as well as bolstering the FDA's emergency response efforts by increasing the capacity for testing of foods for radioactive contamination, intentional or accidental.

The selected laboratories will receive funds to assist in acquiring supplies, personnel, and facility upgrades. The labs will receive training in current food testing methodologies, participate in method development and

validation, proficiency testing, and food defense surveillance assignments.

Two key project areas have been identified for the grant recipients. These areas involve the detection of radioactive contamination, utilizing the most advanced detection systems available.

FERN's mission is to integrate the nation's food-testing laboratories at the local, state, and federal levels into a network able to respond to emergencies involving biological, chemical, or radiological food contamination. The network can respond to emergencies related to agents in food and restore the public's confidence in the food supply.

FOR IMMEDIATE RELEASE :November 19, 2007, Media  
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## **Preventing Health Risks Associated with Drinking Unpasteurized or Untreated Juice**

Content source: National Center for Infectious Diseases

Orange, apple, grape or cranberry- juice comes in many different flavors. Juice provides essential nutrients that help keep people healthy. Consumers today have numerous choices when it comes to drinking juice. One of the decisions they must make is whether to buy pasteurized or unpasteurized juice. Though illness due to juice is rare, several outbreaks of diarrheal illness due to juice have been reported in the United States in the last decade. Most outbreaks of illness due to juice have been linked to untreated or inadequately treated juice products. Most juice sold in the United States is treated. One of the most common treatments used is pasteurization.

### **Some outbreaks of foodborne illness linked to juice:**

**1996:** Outbreak of *E. coli* O157:H7 infections linked to untreated apple juice sold in multiple states

**2003:** Outbreak of *Cryptosporidium* infections linked to apple cider inadequately treated with

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ozone

**2005:** Outbreak of *Salmonella* infections linked to inadequately treated orange juice marketed as ‘fresh squeezed’ and sold in multiple states

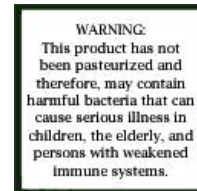
**Pasteurized** juice is heated to a high temperature for a short time before it is sold. By pasteurizing juice, pathogens (germs) which may be present in the liquid are killed. Most juice concentrate sold in grocery stores has been heat treated as part of the concentration process and this is equivalent to pasteurization. About 98% of all juices sold in the United States are pasteurized (1). Pasteurized juice can be found as frozen concentrate, displayed at room temperature or in the refrigerated section of your supermarket. Pasteurized juice products may say “Pasteurized” on their labels. Besides pasteurization, some juices are treated with other processes.

**Treated** juice, more commonly found in health-food stores and farm markets, has been treated to kill pathogens that may be present in the juice through a method other than pasteurization, such as UV irradiation, surface treatment of the fruit or high pressure treatment. Some types of treated juice may be marketed as “fresh squeezed.”

The methods used to treat the juice must have been proven to work and verified by the Food and Drug Administration (FDA). These processes must be carried out properly for the treatment to be successful. If these requirements are not met, the treatment may not be effective in killing pathogens and people who consume the juice may become ill. There have been two recent outbreaks of illness related to inadequately treated juices. One was related to inadequate treatment with ozone and the other to inadequate surface treatment of the fruit. Treated juice products have labels that do not have a warning label like the one below, and do not say “Pasteurized.” Treated unpasteurized juice is safe if it has been properly processed by a proven effective treatment method such as UV irradiation.

**Untreated (raw)** juice has not been treated in any way to kill pathogens that may be present.

This type of juice may be found in the refrigerated sections of grocery stores, health-food stores, cider mills, and farm markets. Another form of untreated juice is untreated cider. One way to make this cider safer is to heat it to at least 170° F. Prepackaged, untreated juice must bear a warning label that looks similar to this one:



To minimize health risk, young children, the elderly and people with weakened immune systems should not consume packaged juice that bears the above warning label or any other form of juice that is known to be untreated (e.g. untreated juice served by the glass at a roadside cider stand). Anyone who wishes to reduce their risk may follow this recommendation. If it is unclear that a juice has been treated to destroy harmful bacteria, avoid drinking it.

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## Draft Compliance Policy Guide Sec. 555.320 *Listeria monocytogenes*

**Introduction:** The purpose of this Compliance Policy Guide is to provide guidance to FDA Staff on FDA's enforcement policy for *Listeria monocytogenes* (*L. monocytogenes*) in foods. 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

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something is suggested or recommended, but not required.

**Background:** *L. monocytogenes* is a pathogenic bacterium that is widespread in the environment and may be introduced into a food processing facility. *L. monocytogenes* can contaminate foods and cause a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, illness (called invasive listeriosis). Foods that have been implicated in outbreaks of invasive listeriosis have been foods that are ready-to-eat (RTE).

RTE foods can be contaminated if ingredients in the foods are contaminated with *L. monocytogenes* and are not treated to destroy viable cells of this pathogen, or if *L. monocytogenes* is allowed to contaminate the RTE food because of improper sanitary conditions or practices. Most RTE foods do not contain detectable numbers of *L. monocytogenes*. For many RTE foods, contamination with *L. monocytogenes* can be avoided – e.g., through the application of current good manufacturing practice requirements that establish controls on ingredients, listericidal processes, segregation of foods that have been cooked from those that have not, and sanitation. Sanitation controls include effective environmental monitoring programs designed to identify and eliminate *L. monocytogenes* in and on surfaces and areas in the plant.

In 2003, FDA and the Food Safety and Inspection Service of the United States Department of Agriculture, in consultation with the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, released a quantitative assessment (the Risk Assessment) of relative risk associated with consumption of certain categories of RTE foods that had a history of contamination with *L. monocytogenes*, or that were implicated epidemiologically with an outbreak or a sporadic case of listeriosis. The Risk Assessment estimated that the risk of listeriosis would vary widely among these food categories.

According to the Risk Assessment, foods estimated to pose the highest risk of being associated with listeriosis are RTE foods that

support the growth of *L. monocytogenes*. Examples of RTE foods that support the growth of *L. monocytogenes* include:

- Milk;
- High fat and other dairy products (e.g., butter and cream);
- Soft unripened cheeses (greater than 50 percent moisture) (e.g., cottage cheese and ricotta cheese);
- Cooked crustaceans (e.g., shrimp and crab);
- Smoked seafood (e.g., smoked finfish and mollusks);
- Raw seafood that will be consumed as sushi or sashimi;
- Many vegetables (such as broccoli, cabbage, and salad greens);
- Non-acidic fruit (such as melon, watermelon, and papaya); and
- Some deli-type salads and sandwiches (particularly those containing seafood and those prepared at retail establishments without acidification and/or the addition of antimicrobial substances).

In contrast, the foods estimated to pose the lowest risk of being associated with listeriosis are foods that, because of intrinsic factors, extrinsic factors, and/or processing factors do not support the growth of *L. monocytogenes*. Intrinsic factors include chemical and physical factors that are normally within the structure of the food, e.g., pH and water activity. Extrinsic factors are those that refer to the environment surrounding the food, e.g., storage temperature. Processing factors include substances added to adjust the pH of food (e.g., acids) and substances that, alone or in combination with other substances, have antimicrobial properties (e.g., sorbates and benzoates). It is well established that *L. monocytogenes* does not grow when:

- The pH of the food is less than or equal to 4.4;

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- The water activity of the food is less than or equal to 0.92; or
- The food is frozen.

Foods may naturally have a pH or water activity that prevents growth of *L. monocytogenes* or processing factors may be deliberately used to achieve those characteristics (e.g., by adding acid to deli-type salads to bring the pH to less than or equal to 4.4). At pH values above 4.4, processing factors generally are used in combination to prevent the growth of *L. monocytogenes* (e.g., sorbates or benzoates may be used in combination with organic acids such as acetic acid, lactic acid, and citric acid in foods such as deli-type salads). The effectiveness of a particular listeristatic control measure in preventing growth in a particular RTE food generally is determined case-by-case, for example, using the results of growth studies specific to the food matrix.

Examples of RTE foods that generally are considered to not support the growth of *L. monocytogenes* include:

- Fish that are preserved by techniques such as drying, pickling, and marinating;
- Ice cream and other frozen dairy products;
- Processed cheese (e.g., cheese foods, spreads, slices);
- Cultured milk products (e.g., yogurt, sour cream, buttermilk);
- Hard cheeses (less than 39 percent moisture) (e.g., cheddar, colby, and parmesan);
- Some deli-type salads, particularly those processed to a pH less than 4.4 and those containing antimicrobial substances such as sorbic acid/sorbates or benzoic acid/benzoates under conditions of use documented to be effective in preventing the growth of *L. monocytogenes*;
- Some vegetables (such as carrots); and
- Crackers, dry breakfast cereals, and other dry foods.

Fruits, vegetables, and cheeses (e.g., soft and semi-soft cheeses) not listed in this CPG may include some products that support growth as well as other products that do not support growth.

**Policy:** FDA will review the available evidence on a case-by-case basis to determine if a food is a RTE food that supports growth or a RTE food that does not support growth.

**Ready-to-Eat Food**  
"Ready-to-eat food" (RTE food) means a food that is customarily consumed without cooking by the consumer, or that reasonably appears to be suitable for consumption without cooking by the consumer.

A food may be considered to be suitable for consumption without cooking by the consumer, and thus a RTE food, even though cooking instructions are provided on the label. For examples, fresh and frozen crabmeat and individually quick frozen (IQF) peas and corn may be RTE foods. Some consumers eat such products without cooking, because they appear to be ready-to-eat.

## **Ready-to-Eat Foods that Support Growth of *L. monocytogenes***

Generally, we intend to consider that a RTE food will support the growth of *L. monocytogenes* if it does not meet the characteristics of a RTE food that does not support growth, as indicated in section III.C.

FDA may regard a RTE food that supports growth of *L. monocytogenes* to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act; the FD&C Act) (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present in the food based on the detection method indicated in section IV.A.

## **Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes***

A RTE food does not support the growth of *L. monocytogenes* if the food: Has a pH that is less than or equal to 4.4; or Is customarily held and consumed in a frozen state; or Has a water

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activity that is less than 0.92; or Is processed using an effective listeristatic control measure (e.g., an antimicrobial substance or a combination of factors such as pH, water activity, and antimicrobial substances).

FDA may regard a RTE food that does not support the growth of *L. monocytogenes* to be adulterated within the meaning of section 402(a)(1) of the Act (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present at or above 100 colony forming units per gram of food (cfu/g)

### Regulatory Action Guidance: Ready-to-Eat Foods that Support Growth of *L. monocytogenes*

The following represents criteria for recommending legal action to CFSAN/Office of Compliance/Division of Enforcement (HFS-605):

*L. monocytogenes* is detected in one or more subsamples of a RTE food that supports the growth of *L. monocytogenes*.

Use Bacteriological Analytical Manual Online, Chapter 10 - "*Listeria monocytogenes*," "Detection and Enumeration of *Listeria monocytogenes* in Foods" as the method for detecting and confirming presence of *L. monocytogenes* (available at <http://www.cfsan.fda.gov/~ebam/bam-10.html>).

### Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes*

Consult with CFSAN/Office of Compliance/Division of Enforcement (HFS-605) before recommending legal action for RTE foods that do not support the growth of *L. monocytogenes*.

### Other Considerations

The criteria in this guidance do not establish an acceptable level of *L. monocytogenes* in food. FDA may choose to take legal action against adulterated food that does not meet the criteria for recommending legal action to CFSAN.

Further, the criteria in this guidance do not excuse violations of the requirement in section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)) that food may not be prepared, packed, or held under insanitary conditions or the requirements in FDA's good manufacturing practices regulation (21 CFR part 110). As set out in 21 CFR 110.80, food manufacturers must take "[a]ll reasonable precautions ... to ensure that production procedures do not contribute contamination from any source."

### Specimen Charges:

#### Domestic Seizure

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce within the meaning of the Act, 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely *Listeria monocytogenes*, which may render it injurious to health.

#### Import Detention

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous or deleterious substance, *Listeria monocytogenes*, which may render it injurious to health.



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## **From the Editor**

Well winter is here, though the temperatures keep changing from warm to cold. As you know we are continuing our efforts to encourage participation in the Bell Ringer, so if you have a story idea, an announcement, or information, please email it to me at [palak.raval-nelson@phila.gov](mailto:palak.raval-nelson@phila.gov). Also, feel free to provide feedback on the articles in the issues or write a letter to the Editor. Lastly, space is available for advertising in the Bell Ringer, just send me the information in an email and I will contact you. I look forward to your feedback and participation. I wish you and yours a happy and safe holiday season.

### **Tentative Schedule of Meetings**

**Spring: March 14, 2008**

**Summer: June 20, 2008**

**Make sure to  
register your email  
on the CASA  
website:  
[http://www.casafdo.  
org/](http://www.casafdo.org/)**

**Hey, do you know some  
one that would make a  
great CASA member?**

**Bring them to a meeting!  
Tell them about CASA!  
Get them to join!**