

Sample Protocol for Evaluating 45 Degree Cold Holding Variance Requests

Purpose

This document provides a sample protocol by which local health jurisdictions (LHJs) in Washington State may evaluate variance requests from food retailers applying for a waiver of the 41°F cold holding requirement. It was created by a small workgroup composed of regulatory and industry partners. It represents the workgroup's best effort to achieve consensus on the technical and practical concerns involved, while ensuring adequate protection of public health.

Background

In 2005, a major revision of Washington State's retail food rule (WAC 246-215) was implemented. This revision merged the state food rule with the US Food and Drug Administration (FDA) 2001 Food Code. The revision was a joint process involving industry, consumer, and regulatory groups. In keeping with the FDA Food Code, the primary cold holding temperature was lowered from 45°F to 41°F. Lowering the refrigeration temperature was mainly done to control the growth of *Listeria monocytogenes*, a pathogenic bacterium that grows much more slowly at 41°F than it does at 45°F.

At the time of the rule change, it was expected that lowering the cold holding temperature would require some retail food establishments to repair or replace some existing refrigeration equipment. To lessen the financial impact of the rule change, the FDA Food Code allows refrigeration equipment able to maintain 45°F but unable to be repaired to hold 41°F to remain in use for 5 years following the adoption of the rule. This provision was adopted and allowed food retailers time to develop the capital plans necessary to upgrade or replace refrigeration equipment by the end of the 5 year period. In Washington State, the 5 year period ends on May 2, 2010.

Discussion

Listeriosis is a potentially serious infection caused by eating food containing *Listeria monocytogenes* (Lm). It is an important public health problem in the United States. The disease mainly affects older adults, pregnant women, newborns, and adults with weakened immune systems. Pregnant women are about 20 times more likely than other healthy adults to become infected with Lm. People living with AIDS are almost 300 times more likely to become infected than people with healthy immune systems. The illness can also rarely affect people without these risk factors. (CDC, 2008)

The Centers for Disease Control (CDC) estimates that 2500 people a year in the United States become very ill with listeriosis. Of these, 500 die. In an average year, the Washington State Department of Health (DOH) receives between 11 and 17 reports of listeriosis and 0 to 5 deaths. In 2007 and 2008, DOH received reports of 25 illnesses and 29 illnesses, respectively. There were 2 reported adult deaths in 2007 and 3 adult deaths in 2008. Miscarriages and stillbirths believed to have been caused by *Listeria* are reported every year.

Most cases of listeriosis do not occur as part of a recognized foodborne illness outbreak. They are instead thought to be “sporadic” cases. Nevertheless, outbreaks do occur. A 2008 Lm outbreak in Canada was responsible for 57 confirmed cases and 22 deaths. The source of the illnesses was ready-to-eat deli meats. In 2002, an 8-state outbreak of listeriosis in the northeastern United States was linked to 46 confirmed cases, 7 deaths, and 3 stillbirths or miscarriages. The outbreak was traced to sliceable turkey deli meat.

The FDA published a risk assessment for foodborne Lm in 2003¹. The assessment included many examples of original scientific research into the impact of temperature on Lm growth rates. According to these studies, Lm grows much more slowly at 41°F than it does at 45°F. The FDA also estimated that lowering the cold-holding temperature to 41°F would reduce actual cases of listeriosis in older adults by more than 90%, if all food retailers complied with the requirement. The new cold holding temperature is an important safety control. It reduces the risk of Lm growing to illness-causing levels in refrigerated foods.

Before an LHI can grant a variance, the operator applying for the variance must show how the public health hazards addressed by the relevant code sections will be otherwise addressed (8-103.11(B)). To justify a variance from the 41°F cold holding requirement, an applicant will need to show that the alternative proposal will provide a comparable level of safety.

Two Reviewed Options for a Variance

The workgroup reviewed two alternative proposals for controlling Lm growth in refrigerated foods. The workgroup found that each proposal provides a level of protection comparable to lowering the cold holding temperature to 41°F. Other acceptable approaches may exist, but the workgroup only reviewed these two:

OPTION 1: Categorize all Foods According to Risk

Because of differences in the chance of contamination, differences in the rate of bacterial growth, and their connection to past listeriosis cases, some foods are more likely than others to cause listeriosis. In its risk assessment, the FDA ranked many kinds of food according to their Lm risk. They did this by estimating the number of cases per year caused by eating those foods. FDA then grouped these kinds of food into the following high, moderate, and low risk categories based on the number of expected Lm cases per year:

High Risk:

- Deli Meats: such as bologna, ham, turkey, roast beef, chicken, and the meat portion of sandwiches – both pre-sliced and sliced at a deli counter
- Frankfurters: such as hot dogs made from any meat or combination of meats
- Pâté and Meat Spreads: such as liver pâté and other meat spreads
- Unpasteurized Fluid Milk: such as raw cow’s milk, raw goat’s milk, and other raw non-bovine milk

¹ “[Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods](http://www.foodsafety.gov/~dms/lmr2-toc.html)” Retrieved from the internet on 6/17/2009. <http://www.foodsafety.gov/~dms/lmr2-toc.html>

- Smoked Seafood: such as smoked salmon, trout, herring, oysters, and other smoked fish not identified as to species. Both hot and cold smoked products are included in this category
- Cooked Ready-to-Eat Crustaceans: such as cooked crab and shrimp; includes imitation crab.

Moderate Risk:

- High Fat and Other Dairy Products: such as butter, cream, half-and-half, and shakes
- Soft Unripened Cheese: such as cottage cheese, baker's cream, American-type Neufchatel cheese, cream cheese, and ricotta
- Fresh Soft Cheese (pasteurized): such as queso panela and queso fresco²
- Pasteurized Fluid Milk: such as pasteurized cow milk, goat milk, and chocolate milk
- Deli-type Salads produced on-site in a retail food establishment³

Low Risk:

- All foods not in the high or moderate risk categories
- Preserved Fish: includes pickled or marinated fish, such as ceviche, pickled herring, dried and salted cod, and non-specified dried fish
- Raw Seafood: such as flounder, pompano, tuna, sturgeon roe, squid, oysters, and sushi
- Fruits: such as raw fruits, dried fruits, and fruit salads
- Dry/Semi-dry Fermented Sausages: such as Lebanon bologna, mortadella, pepperoni, and salami
- Semi-soft Cheese: such as Edam, Gouda, havarti, Limburger, Monterrey jack, Muenster, and provolone
- Soft Ripened Cheese (pasteurized): such as Brie, Camembert, feta, and mozzarella
- Vegetables: such as raw vegetables, cooked vegetables, and vegetable salads.
- Deli-type Salads commercially manufactured at a food processing plant: such as meat, seafood, egg, and pasta salads
- Ice Cream and Other Frozen Dairy Products: such as frozen yogurt, ice milk, ice cream mix, and novelty ice cream products
- Processed Cheese: such as cheese food, cheese spreads, cheese sauces, and cheese slices
- Cultured Milk Products: such as buttermilk, yogurt, and sour cream
- Hard Cheese: such as cheddar, Emmentaler, Gruyere, parmesan, Queso Chihuahua, Romano, Stilton, and Swiss

Under this option, the food retailer agrees to keep all high and moderate risk foods at 41°F or less. Low risk foods may be held at 45° F or less in qualifying refrigeration equipment. According to the FDA's risk assessment, all categories of low risk foods are

² While the FDA classified pasteurized Fresh Soft Cheeses as low-risk foods, the workgroup moved them to the moderate risk category because of the frequency of recalls due to Lm in these products and their increasing popularity with consumers.

³ While the FDA classified all deli salads as low-risk foods, the workgroup moved those produced in-house into the moderate risk category because they may contain other moderate or high-risk foods as ingredients, and are not formulated to control bacterial growth.

expected to cause less than one case of listeriosis per year nationwide. Most low-risk food categories have a predicted number of Lm cases of less than 0.1 per year nationwide. On this basis, allowing food retailers to store low risk foods at 45°F for an additional two years in qualifying refrigeration equipment is not expected to have any observable impact on public health in Washington State.

Option 1 Recommendations:

The workgroup recommends that LHJs consider approving variance requests from food retailers using Option 1, with the following conditions:

1. The food establishment applying for a variance must provide a report from a licensed refrigeration contractor indicating that the specific refrigeration equipment in question is not capable of holding refrigerated food at 41°F or less, but is capable of holding food at 45°F or less. Equipment requiring only adjustment or repair in order to hold food at 41°F is not eligible for a variance.
2. Only refrigeration equipment that was in place and in use prior to May 2, 2005 is eligible for a variance.
3. Only low-risk foods may be stored in qualifying refrigeration equipment at 45°F or less.
4. The variance should have an initial term of no more than two years.
5. Refrigeration equipment covered by the variance may not be used to cool hot food.
6. When an LHJ finds food above 45°F in refrigeration equipment covered by a variance, the food may be discarded as indicated in the DOH model Food Reconditioning and Destruction Guidelines or as indicated in the local food destruction policy, if one exists.
7. Repeated failure to comply with the terms of the variance will result in progressive enforcement actions and may result in the revocation of the variance.
8. The LHJ may remove the variance if competing food safety rules are implemented.
9. The LHJ may remove the variance if:
 - a. they determine that the variance contributed to one or more known cases of foodborne illness, or
 - b. DOH determines, based on public health disease data, that such variances have led to an unexpected increase in the incidence of foodborne illnesses.

OPTION 2: Limit Food Storage Time

Even when Lm is present in food, it will not cause illness unless the number of bacteria grows to the dose needed to make people sick. Since Lm bacteria grow more quickly at 45°F, foods contaminated with Lm would be expected to reach an illness-causing dose more quickly at 45°F than at 41°F. Limiting the amount of time the food can be stored at 45°F may, therefore, achieve a reasonably equivalent reduction in risk when compared to lowering the cold holding temperature to 41°F.

According to an FDA baseline study cited in the risk assessment, about 12 percent of refrigerators at retail hold food at temperatures of more than 45°F. By FDA's analysis, this small minority of refrigerators is responsible for almost 70 percent of all listeriosis cases. In this context, the FDA found that limiting the time of storage as a single intervention was not as effective as lowering food temperatures. If, however, two

interventions are applied at the same time so that 45°F cold holding is properly performed **and** the time of storage is limited to 7 days or less, the risk reduction is predicted to be comparable to lowering the cold holding temperature to 41°F.

This option requires food retailers to identify a discard date on each package or container of potentially hazardous food to be stored at 45°F. This discard date shall be no more than 7 days from the date the food is placed into 45°F cold holding. The discard date mark on the package of food may follow a coding system approved by the LHJ (like a color-coded sticker corresponding to a documented date), and does not have to be a printed calendar date.

Option 2 Recommendations:

The workgroup recommends that LHJs consider approving variance requests from food retailers using Option 2, with the following conditions:

1. The food establishment applying for a variance must provide a report from a licensed refrigeration contractor indicating that the specific refrigeration equipment in question is not capable of holding refrigerated food at 41°F or less, but is capable of holding food at 45°F or less. Equipment requiring only adjustment or repair in order to hold food at 41°F is not eligible for a variance.
2. Only refrigeration equipment that was in place and in use prior to May 2, 2005 is eligible for a variance.
3. All potentially hazardous food to be held at 45°F or less in qualifying refrigeration equipment shall be marked to indicate the discard date.
4. The discard date shall be no more than 7 calendar days from the date the food is placed into 45°F cold holding, or the manufacturer's use-by date, whichever comes first. The day the food goes into 45°F cold holding is counted as day one.
5. All such food shall be sold or discarded by the date indicated. Food past its coded discard date may not be donated to charity or given away to the public.
6. On a daily basis, the food establishment must check and write down the temperature of at least one food product in every piece of refrigeration equipment covered by the variance.
7. The variance should have an initial term of no more than two years.
8. When an LHJ finds food above 45°F in refrigeration equipment covered by a variance, the food may be discarded as indicated in the DOH model Food Reconditioning and Destruction Guidelines or as indicated in the local food destruction policy, if one exists.
9. Repeated failure to comply with the terms of the variance will result in progressive enforcement actions and may result in the revocation of the variance.
10. The LHJ may remove the variance if competing food safety rules are implemented.
11. The LHJ may remove the variance if:
 - a. they determine that the variance contributed to one or more known cases of foodborne illness, or
 - b. DOH determines, based on public health disease data, that such variances have led to an unexpected increase in the incidence of foodborne illnesses.